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Sex, Science, and the Age of Anxiety

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"'When you hear somebody say, "This is not about money"—it's about money.' And when you hear somebody say, 'This is not about sex'—it's about sex."[1]

–Senator Dale Bumpers

"In America today, there is an unprecedented assault on the human right to exercise informed consent to medical risk-taking. It is being led by one of the most powerful and wealthy corporate empires in the world: the global pharmaceutical industry. . . . What is at stake for the American people is our health and our liberty."[2]

–Barbara Loe Fisher, anti-vaccination activist

I. INTRODUCTION

Imagine a vaccine that could protect against multiple types of cancer and prevent the death of thousands of Americans each year, as well as the enormous financial costs and psychological stresses of annual medical-screening exams and invasive biopsies.[3] One might suppose that such a vaccine would be hailed as a minor miracle and that both government and private citizens would embrace this medical advance and the opportunity it presents to enhance both individual and public health. Indeed, in Australia the government pays for all chil-

1. Senator Dale Bumpers, channeling H. L. Mencken in his closing defense argument at the Senate impeachment trial of President William J. Clinton (Jan. 21, 1999), *available at* http://americanrhetoric.com/speeches/dalebumpersdefenseofclinton.htm (last visited July 29, 2011).
2. Barbara Loe Fisher, *The Health Liberty Revolution & Forced Vaccination,* NAT. VACCINE INFO. CENTER (Aug. 24, 2011, 11:32 PM), http://www.nvic.org/nvic-vaccine-news/august-2011/the-health-liberty-revolution—-forced-vaccination.aspx.
3. *See, e.g.*, Sabrina Tavernise, *HPV Vaccine Is Credited in Fall of Teenagers' Infection Rate,* N.Y. TIMES, Jun. 19, 2013, at A1; Gardiner Harris, *Panel Endorses HPV Vaccine for Boys of 11,* N.Y. TIMES, Oct. 25, 2011, at A1 (citing public health expert Dr. William Schaffner, who declared about the humanpapilloma virus (HPV) vaccine, "'This is cancer, for Pete's sake. . . . A vaccine against cancer was the dream of our youth.'"). *See infra* Part III. HPV causes cancer of the cervix, vagina, vulva, oropharynx, anus, and penis. Ahmedin Jemal et al., *Annual Report to the Nation on the Status of Cancer, 1975–2009, Featuring the Burden and Trends in Human Papillomavirus (HPV)—Associated Cancers and HPV Vaccination Coverage Levels,* 105 J. NAT'L CANCER 175, 175–76 (2013) [hereinafter *Annual Report on the Status of Cancer*].

dren to be immunized against this disease.[4] But in the United States opposition to this vaccine, and particularly to the possibility of mandatory immunization, has led to intense controversy, preventing many children, soon to be adults, from obtaining protection against the risk of developing fatal cancer.[5] The vaccine at issue, if you have not already guessed it, is the vaccine against the human papillomavirus (HPV).

The contention that surrounds the HPV vaccine is the latest skirmish in the culture wars. The fight is over sex, science, and whether government or individuals should take the lead to preserve the nation's posterity.[6] HPV is the most common sexually transmitted disease in the United States, with about twenty million Americans being infected at any one time.[7] HPV not only causes many types of cancer but also genital warts, which are embarrassing and stressful to many.[8] The debate over mandatory HPV vaccination illuminates a significant political divide in American society at the same time that it

4. Tony Kirby, *Australia to Be First Country to Vaccinate Boys Against HPV*, 13 LANCET ONCOLOGY e333 (2012); Mona Saraiya & Susan Hariri, *HPV Vaccine Effect: Is the Glass Half Full or Half Empty*, 377 LANCET 2057, 2057 (2011) .

5. Dan M. Kahan et al., *Who Fears the HPV Vaccine, Who Doesn't, and Why? An Experimental Study of the Mechanisms of Cultural Cognition*, 34 L. & HUM. BEHAV. 501, 511–12 (2010) (describing the ways in which unconscious psychological and cultural views predispose people to oppose or support the HPV vaccination); Laurie E. Markowitz et al., *Quadrivalent Human Papillomavirus Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MORBIDITY & MORTALITY WKLY. RR-2, at 2–4 (Mar. 23, 2007) (describing the design and efficacy of Merck's Gardasil®, a vaccine effective against four virulent strains of HPV); Jemal, *supra* note 3, at 185 (noting that less than half of all age-eligible American girls had received one or more of the three recommended doses of the HPV vaccine, with rates varying from less than 30% to more than 70% in some states).

6. Here I am using "posterity" both literally to refer to the descendants of any one person, as well as all future generations, and figuratively, gesturing at the concerns frequently articulated by politicians, that a particular action is necessary to preserve "our way of life." *See, e.g.*, statement by Paul Ryan, the 2012 Republican candidate for Vice President, who declared, in reference to a potential second Obama term, "It's a dangerous path . . . that grows government, restricts freedom and liberty, and compromises those values, those Judeo-Christian, western civilization values that made us such a great an exceptional nation in the first place." Shushannah Walshe, *Paul Ryan Says Obama Would Compromise 'Judeo-Christian Western Civilization Values,'* ABC NEWS (Nov. 4, 2012, 11:55 PM), *available at* http://abcnews.go.com/blogs/politics/2012/11/paul-ryan-says-obama-would-compromise-judeo-christian-western-civilization-values/.

7. David Bruce, *HPV Vaccination Being Given to Boys More Frequently*, PITTSBURGH POST-GAZETTE, Jan. 1, 2012, at A-13. For further discussion of the epidemiology of HPV, see discussion *infra* Part III.A.

8. Bruce, *supra* note 7, at A-13; *see also* Jemal, *supra* note 3, at 176 (stating one of the goals of the HPV vaccination is to prevent anogenital warts); *see also* Kirby, *supra* note 4 (stating the greatest direct effect of the HPV vaccination for boys will be the decrease in their incidence of genital warts and that vaccinating boys also protects unvaccinated girls).

triggers a reconsideration of the medical and legal justifications for mandatory actions to protect the public's health. A century after the Supreme Court, in *Jacobson v. Massachusetts*,[9] upheld compulsory smallpox vaccination as an essential form of collective action necessary to the physical preservation of the polity,[10] the social compact underlying much of the modern democratic state is beginning to fray. The fact that the HPV vaccination implicates sex, one of life's most pleasurable activities, makes the discussion of mandatory vaccination both more complex and more interesting. However, the core issue in the vaccination debate is whether the government has the right to insist, with limited opportunities for parents to opt out for religious reasons, that children be exposed to a tiny but real risk of injury and even death in order to protect those children, as well as other children and adults, from a much greater risk of harm.[11] This Article asserts that it does.

This issue was raised indirectly in the U.S. Supreme Court's 2011 decision in *Bruesewitz v. Wyeth LLC*.[12] In *Bruesewitz*, the Court held that the National Childhood Vaccine Injury Act of 1986[13] preempted all defective design tort suits against vaccine manufacturers, effectively precluding state common law suits.[14] The Court's decision left many parents who believed that their children had been injured by vaccination without a remedy.[15] Mandatory HPV vaccination became a hot topic in the 2012 presidential campaign, embroiling several Republican presidential candidates. Texas Governor Rick Perry was vilified, accused of sacrificing innocent young girls on the altar of political ambition by seeking to curry favor with the pharmaceutical giant Merck when he issued an executive order mandating that sixth-grade girls be vaccinated against HPV.[16] On the campaign trail, Representative Michele Bachmann asserted that mandating HPV vaccination was a dangerous policy, relying on a conversation she had with a woman whose daughter had "become mentally retarded" as a result of

9. Jacobson v. Commonwealth of Mass., 197 U.S. 11 (1905).

10. *Id.* at 27–29.

11. *See* discussion *infra* subsection II.A.1.

12. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068 (2011).

13. 42 U.S.C. §§ 300aa-2–300aa-33 (2006).

14. *Bruesewitz*, 131 S. Ct. at 1082.

15. Because many parents have been unsuccessful in receiving compensation through the administrative tribunal established by the Act, due to an inability to establish a causal relationship between their child's injury or illness and vaccination, they viewed state law causes of action as their last option in the pursuit of a remedy for their children. SETH MNOOKIN, THE PANIC VIRUS 295–96 (2011); *cf. Bruesewitz*, 131 S. Ct. at 1086 (Sotomayor, J., dissenting); *see also* Fisher, *supra* note 2 (reflecting the extreme views of a small but growing group of parents).

16. Chris Tomlinson, *Perry Faces New Heat for Vaccine Order; Presidential Hopeful Defends Himself, Calls Action Mistake,* CHIC. SUN-TIMES, Sept. 14, 2011, at 38.

receiving the vaccine.[17] Bachmann's statement was condemned by the American Academy of Pediatrics[18] and others, who charged that her statement not only lacked scientific support, but that it could also discourage childhood vaccination and thus harm the public's health.[19] As the 2012 presidential campaign unfolded, accusations that the Republican Party was engaged in a "war on women" multiplied, which included denying women access to a broad array of reproductive health care services.

This Article examines the question of whether the HPV vaccine should be mandated (for girls and/or boys) in the context of declining rates of childhood immunization and the potential threat to public health that this decline poses.[20] The Article addresses two interconnected legal issues: first, whether mandating vaccines to prevent the spread of disease is constitutional under substantive due process and equal protection principles, and second, whether parents should be permitted to "opt out" of mandatory vaccination on their children's behalf, either for all vaccines or those which prevent particular diseases. The Article addresses these issues in the context of America's growing concern about the risks to children's health and considers how our society's scientific literacy (or lack thereof) affects the response to risk.

A. A Road Map

The next section (Part I.B.) briefly sketches current vaccine controversies, focusing on special concerns raised about the HPV vaccina-

17. Marie McCullough, *Scientist Challenges Bachmann Claim*, PITTSBURGH POST-GAZETTE, Sept. 16, 2011, at A-3; *see also* Laura Bassett, *Rick Perry's HPV Vaccine Law Sparks Political Fight That Ignores Health Issues*, HUFFINGTON POST (Sept. 13, 2011, 7:36 PM), http://www.huffingtonpost.com/2011/09/13/rick-perry-hpv-vaccine_n_961159.html (stating Bachmann criticized Rick Perry for his proposed vaccine mandate).

18. Press Release, American Academy of Pediatrics, American Academy of Pediatrics Statement on HPV Vaccine (Sept. 13, 2011), http://www2.aap.org/advocacy/releases/hpv2011.pdf.

19. *Id.*; Denise Grady, *Remark on Vaccine Could Ripple for Years*, N.Y. TIMES, Sept. 20, 2011, at D1.

20. Throughout this Article, I will use the terms "immunization" and "vaccination" interchangeably. Immunization is a process that, through inoculation, makes it possible for humans to develop their own antibodies to fight foreign bodies that cause diseases. Vaccination (inoculation with a vaccine) is the way that most people develop permanent immunity to a disease, although such immunity can also be derived passively (as when a pregnant woman passes along her own antibodies to the developing fetus). Immunity is also developed if one is exposed to the disease itself. The term vaccination is derived from the Latin *vacca* (cow) because of the use of cowpox to inoculate humans against the similar virus smallpox. CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 1–4 (William Atkinson et al. eds., 12th ed. 2012); CONCISE OXFORD ENGLISH DICTIONARY (Angus Stevenson & Maurice Waite eds., 12th ed. 2011).

tion. Part II examines current law and science governing vaccination, connecting constitutional, regulatory, and tort law doctrines. This Part first considers the legal and scientific justifications for government vaccination mandates. It then addresses the role of informed consent in vaccination, focusing on the recent upsurge in parental efforts to opt out of vaccination for their children and examining the consequences of state laws that broaden the criteria for religious or "philosophical" exemption. Next, the Article reviews current federal oversight of vaccine safety and considers whether it is sufficient to protect children and adults from vaccination-related harms. Here, the Article offers informed speculation about the impact of the Supreme Court's decision in *Bruesewitz*.[21]

In Part III, the Article addresses concerns about the HPV vaccination. First, it explores medical and epidemiological data to address the question of whether mandatory (as distinguished from recommended) vaccination is necessary to reduce the incidence of HPV-related death, sterility, and illness. Second, it addresses legal and constitutional concerns raised by HPV's transmissibility through sexual contact. Although the HPV vaccine was originally approved and recommended only for girls because of the strong connection between HPV infection and cervical cancer, the vaccine is now approved and recommended for boys as well.[22] The latter recommendation and approval reflects the vaccine's efficacy in reducing the transmission of HPV between males and females and also in reducing the rising male-to-male transmission rate, which together have led to an increase of HPV-caused cancers in males.[23] The Article will consider both the substantive due process concerns applicable to all mandatory vaccination programs, particularly those targeted at children, and the equal protection concerns that could be raised by a vaccine mandate that targets only one gender.

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21. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068 (2011).

22. Harris, *supra* note 3.

23. *Id.*; *see also* Jemal, *supra* note 3, at 194 (noting a study which found that men having sex with men have the highest anal cancer incidence rate in California); American Academy of Pediatrics, *Committee on Infectious Diseases, HPV Vaccine Recommendations*, 129 PEDIATRICS 602, 603 (2012) [hereinafter *HPV Vaccine Recommendations*], *available at* http://pediatrics.aappublications.org/content/129/3/602.full.html (last visited Feb. 19, 2013) (noting that studies show a high incidence of precancerous lesions of the anus among men having sex with men, suggesting but not establishing that the HPV vaccine could be important in preventing anal cancer among this group); Jeremy Laurance, *Gay Men Must Receive Cancer Vaccine for Girls, Says BMA; Doctors Urge Minister to Take Action over Alarming Increase in Anal Cancer*, INDEP. (London), Jan 17, 2013, at 6 (noting the rising incidence of anal and throat cancer among young gay and bisexual men in Britain and in most of the developed world); Donald G. McNeil Jr., *HPV Vaccine Found to Help with Cancers of Throat*, N.Y. TIMES, July 19, 2013, at A6 (noting the rising incidence of HPV-caused throat cancer among middle-aged heterosexual men is due to an increase in oral sex).

Part IV concludes, recommending that all jurisdictions enact laws mandating vaccination of middle school students of both genders against HPV, subject to the same opportunity for parents to claim a medical, religious, or philosophical exemption that applies to all other vaccine-preventable diseases.

B. The Problem

Across America, there is a growing backlash against vaccination, resulting in declining childhood immunization rates.[24] This is occurring even though most people understand that vaccinations are vitally necessary to decrease the incidence of diseases, particularly those that are caused by airborne organisms and are spread by casual contact.[25] When the vast majority of a population is vaccinated against a disease, it becomes much harder for that disease to spread, as the means of disease transmission are interrupted. This phenomenon is known as "herd immunity."[26] Herd immunity protects very young children, pregnant women, elderly people, and people with compromised immune systems, who often cannot be vaccinated, as well as those people for whom vaccination does not "take."[27] The extent of vaccination nec-

24. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 32, Appendix G-8; The Associated Press, *Fewer Kids Getting Vaccines; Parents Opting out of School Shots Due to Fears, Paranoia, Laziness*, DAILY NEWS (Nov. 29, 2011, 1:33 PM), http://www.nydailynews.com/life-style/health/kids-vaccines-parents-opting-school-shots-due-fears-paranoia-laziness-article-1.984004#ixzz2M3C7PKhk; David Ropeik, Editorial, *Not Vaccinated? Not Acceptable*, L.A. TIMES, July 18, 2011, at 11; Trine Tsouderos et al., *Vaccine Rates Raise Risk of Outbreaks; More Schools Fall Below State's Recommended Protection Level*, CHI. TRIB., June 19, 2011, at C1.

25. Strictly speaking, a distinction may be drawn between infectious diseases, which are caused when microorganisms enter the body and grow within it; contagious diseases, which are transmitted either by direct or indirect contact with infected individuals or their bodily discharges; and communicable diseases, which are communicated from person to person, animal to animal, animal to person, or person to animal, either directly or indirectly. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1993). In practice, most laypeople, as well as the OXFORD ENGLISH DICTIONARY (6th ed. 2007), use the terms interchangeably.

26. Walter A. Orenstein et al., *Public Health Considerations—United States*, *in* VACCINES 1006 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999); Geoffrey P. Garnett, *Role of Herd Immunity in Determining the Effect of Vaccines Against Sexually Transmitted Disease*, 191 (Supp. 1) J. INFECTIOUS DISEASES S97 (2005).

27. INST. OF MED., FINANCING VACCINES IN THE 21ST CENTURY—ASSURING ACCESS AND AVAILABILITY 3, 27 (2004) [hereinafter FINANCING VACCINES] (discussing the protection of infants and nonvaccinated persons); Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, *in* LAW IN PUBLIC HEALTH PRACTICE 262, 264 (Richard A. Goodman et al. eds., 2003); *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, PARENT'S GUIDE TO CHILDHOOD IMMUNIZATIONS 38 (2010), http://www.cdc.gov/vaccines/pubs/parents-guide/downloads/parents-guide-508.pdf (discussing the benefits of herd immunity for children); U. Okla. Health Scis. Ctr., Employee Vaccinations Help Protect Nursing Home Residents (Sept. 9, 2011), http://www.ouhsc.edu/news/

essary to achieve herd immunity varies with each disease's infectiousness.[28] For example, herd immunity against polio is achieved by community immunization rates of about eighty percent, while more than ninety percent is necessary for measles.[29] When immunization rates are low, especially in specific localities, the risk of a disease outbreak increases.[30] In 2011, for example, the number of measles cases nationwide was higher than at any point in the last fifteen years.[31] The problem is exacerbated by the global trend of increased travel.[32] When non-immunized children travel abroad, they can readily contract a disease and bring it home, infecting not only unvaccinated children but also others vulnerable to the disease.[33]

Since the push to develop a vaccine to prevent polio, the government has worked with vaccine manufacturers to develop vaccines to prevent diseases that strike broad swaths of the population.[34] Hepatitis B vaccine was the first cancer-preventative vaccine,[35] followed by the HPV vaccines, which target the most common strains of the human papillomavirus, all of which have been shown to cause cervical cancer, other cancers, and genital warts.[36] Two of these strains, HPV-

templates/?a=484 (discussing the importance of herd immunity in nursing homes).

28. Malone & Hinman, *supra* note 27, at 264.
29. *Id.*
30. "'[V]accine refusal clusters geographically (and perhaps in social networks). . . . Therefore, even if only ten of 100 people refuse vaccines but most of them live in the same neighbourhood, the likelihood of outbreaks increases due to local breakdown of herd immunity.'" Priya Shetty, *Experts Concerned About Vaccination Backlash*, 375 LANCET 970, 970 (2010) (quoting Emory University Professor Saad Omer).
31. Associated Press, *2011 Measles Outbreak Worst Since 96*, BOS. GLOBE, Apr. 30, 2012, at A2, 22; Letitia Stein, *Measles Cases Rise As More Shun Shot*, ST. PETERSBURG TIMES (Fla.), July 8, 2011, at 1B.
32. Yvonne A. Maldonado, *Current Controversies in Vaccination*, 288 JAMA 3155, 3156 (2002).
33. Associated Press, *supra* note 31, at A2; Stein, *supra* note 31, at 1B.
34. *CDC's Race to Eradicate Polio*, CENTERS FOR DISEASE CONTROL & PREVENTION (Nov. 6, 2012), http://www.cdc.gov/features/polioeradication/index.html.
35. The vaccines against Hepatitis B and HPV, the human papillomavirus, are designed to prevent infection with strains of these organisms, which, if untreated, lead to cancer. Infection with the Hepatitis B virus leads to acute, and then chronic, hepatitis. In some cases this progresses to cancer. The Hepatitis B virus is the cause of up to eighty percent of all hepatocellular carcinomas (cancers of the liver). CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 115–17. It also leads to an estimated 5000 deaths per year due to cirrhosis and liver cancer. Daniel B. Fishbein et al., *New, and Some Not-So-New, Vaccines for Adolescents and Diseases They Prevent*, 121 PEDIATRICS S5, S10 (2008).
36. Jemal, *supra* note 3, at 175–76. There are two FDA-approved vaccines against HPV. Gardasil® was developed by Merck Pharmaceuticals and targets the four most common strains of HPV, strains 6, 11, 16, and 18. Cervarix® was developed by GlaxoSmithKline and targets HPV-16 and HPV-18, which cause both cervical cancer and throat cancer. NAT'L CANCER INST., *Fact Sheet—Human Papil-*

16 and HPV-18, are estimated to cause 7000 cases of cancer in men and 15,000 cases of cancer in women annually,[37] including more than seventy percent of cervical cancer cases.[38] Approximately 12,000 American women are diagnosed with cervical cancer each year, and nearly 4200 American women die annually from the disease.[39] HPV infection can also lead to other types of cancers, causing more than 1500 additional deaths annually. These include throat cancer, anal cancer (which affects both men and women), and vulvar cancer (affecting only women, with forty percent of these deaths being attributable to HPV).[40] Some forms of penile, vaginal, urethral, and head and neck cancers are also caused by HPV.[41] HPV causes anogenital warts, which will affect ten percent of American men and women throughout

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lomavarius (HPV) Vaccines (Dec. 29, 2011), http://www.cancer.gov/cancertopics/factsheet/prevention/HPV-vaccine [hereinafter *Fact Sheet*]; Ctrs. for Disease Control & Prevention, *Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males—Advisory Committee on Immunization Practices (ACIP), 2011*, 60 MORBIDITY & MORTALITY WKLY. 1705 (Dec. 23, 2011), *available at* http://www.cdc.gov/mmwr/pdf/wk/mm6050.pdf. HPV types 16 and 18 are responsible for multiple forms of cancer. *See infra* note 37.

37. According to the American Academy of Pediatrics, "HPV types 16 and 18 . . . are responsible for 70% of cases of cervical, 87% of anal, 60% of oropharyngeal [throat], and 31% of penile cancers." *HPV Vaccine Recommendations*, *supra* note 23, at 603; *see also* Tavernise, *supra* note 3 (proclaiming that "[t]he virus causes about 19,000 cancers in women every year, and 8,000 in men").

38. Markowitz, *supra* note 5, at 2–4.

39. Roni Caryn Rabin, *A Vaccine May Shield Boys Too*, N.Y. TIMES, Jul. 19, 2011, at D5; Markowitz, *supra* note 5, at 1. These numbers may be usefully compared not only with other adult cancer deaths, but also with the number of children who die each year from vaccine-preventable diseases such as chicken pox (as recently as 2007, fourteen people died; in the 1970s and 1980s deaths frequently exceeded 100 annually. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at G-5–G-6). Drowning causes more than 1000 deaths a year, and motor vehicle and other transportation accidents cause more than 6500 a year. NAGESH N. BORSE ET AL., CDC CHILDHOOD INJURY REPORT: PATTERNS OF UNINTENTIONAL INJURIES AMONG 0–19 YEAR OLDS IN THE UNITED STATES, 2000-2006 3 (2008), *available at* http://www.cdc.gov/safechild/images/CDC-childhoodinjury.pdf.

40. Throat cancer is increasing, particularly among men, and the proportion of throat cancers attributable to the HPV virus, rather than other carcinogens, is also increasing, as both men and women have switched to oral sex in the belief that it is a safer form of sexual activity). Bonnie Miller Rubin, *HPV Connected to Oral Cancers Too*, CHIC. TRIB., Feb. 15, 2012, at Chicagoland Health and Family Section, 2; Denise Grady, *Study Cites Increase in Cancers from HPV*, N.Y. TIMES, Oct. 4, 2011, at D5 (citing Anil K. Chaturvedi et al., *Human Papillomavirus and Rising Oropharyngeal Cancer Incidence in the United States*, J. CLINICAL ONCOLOGY 29 (2011), *available at* http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2011.36.4596); McNeil, *supra* note 23.

41. Jemal, *supra* note 3, at 185. All together, cancers caused by HPV account for more than three percent of female cancer cases and two percent of male cancer cases diagnosed in 2009. *Id.*

their lifetimes.[42] Recently, HPV has been linked with heart disease, but so far only an association, rather than causation, has been shown.[43]

Vaccines are the victims of their own success.[44] In the 1950s, more than 2000 Americans died *each year* from diseases that are now preventable by vaccines.[45] Before they were brought under control in the second half of the twentieth century, more than 1.1 million Americans were infected with those diseases each year.[46] Data on three of the most deadly diseases are illustrative. In 1950 alone there were 120,000 cases of pertussis (whooping cough) and 1118 deaths from that disease, as well as 33,000 cases of polio, with 1904 deaths. By 2007, there were no cases of polio; there were, however, 10,454 cases of pertussis, with nine deaths. In 2010, California had the largest outbreak of pertussis in sixty years, with ten California children dying.[47] Today one-fifth of all children who contract pertussis are hospitalized, with complications including pneumonia, seizures, and encephalopathy.[48] In 1950, there were 319,000 cases of measles, with 468 deaths; in 2007 there were 43 cases and no deaths,[49] although there was a major outbreak of measles in 2011.[50]

Today, it is estimated that giving the standard set of childhood vaccines to American children prevents more than 42,000 deaths and twenty million cases of disease for each birth cohort, saving nearly $14 billion in direct heath care costs and $69 billion in broader costs to society.[51] Yet, in an era in which most parents and many health care

42. Debbie Saslow et al., *American Cancer Society Guideline for Human Papilomavirus (HPV) Vaccine Use to Prevent Cervical Cancer and Its Precursors*, 57 CA CANCER J. CLIN. 7, 9 (2007).

43. Denise Grady, *Troubles with Heart Are Linked to HPV*, N.Y. TIMES, Oct. 25, 2011, at D5.

44. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1072 (2011). *See also* Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 359, 362 (2004) (discussing how "[v]accines have become a victim of their tremendous success").

45. In some years, particularly before 1954, when the polio vaccine was introduced, the deaths exceeded 3500 annually. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at G-1, G-3, G-7.

46. Malone & Hinman, *supra* note 27, at 266.

47. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at G-1–G-2; *see also* JENNIFER BRESHEARS WHEELER, NAT'L CONFERENCE OF STATE LEGISLATURE, IMMUNIZATIONS AND THE AFFORDABLE CARE ACT (April–May 2011), www.ncsl.org/research/health/immunizations-and-the-affordable-care-act.aspx. (discussing the important role vaccines play in preventing diseases).

48. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 216.

49. *Id.* at G-3–G-4.

50. Associated Press, *supra* note 31, at A2; Stein, *supra* note 31, at 1B.

51. Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—United States, 2001–2010*, 60 MORBIDITY & MORTALITY WKLY. REP. 619, 619 (2011) (citing F. Zhou, Updated Economic Evaluation of the Routine Childhood Immunization Schedule, presented at the 45th National Immunization Confer-

providers have never seen a child afflicted with polio, pertussis, or measles,[52] a small but growing number of parents are focused, not on the risk that their child might contract a disease preventable by vaccination but on the fear that vaccination itself could cause autism or other childhood diseases for which current scientific explanations are either incomplete or discomforting.[53]

Opponents of vaccination have floated many theories asserting that vaccines promote, rather than prevent, disease. These theories lack scientific merit; they have been uniformly tested and rejected.[54] Nonetheless, some parents are still fearful that vaccines are not safe for their children, and many others are simply unsure.[55] Some anti-vaccine advocates claim that autism, an often devastating disease,[56] is caused by exposure to thimerosal, which was formerly used as a preservative in many childhood vaccines, especially DPT (now DTaP).[57]

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ence, Washington, D.C. March 28–31, 2011), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm (last visited Aug. 29, 2013).

52. Kathryn M. Edwards, *State Mandates and Childhood Immunization*, 284 JAMA 3171, 3171 (2000).

53. Tsouderos, *supra* note 24; *see also* Elliot Njus, *High Opt-Out Rate for Vaccinations Challenges Clark County*, OREGONIAN (Portland, Or.), June 18, 2011 (discussing parents' fear of vaccinations and their correlation with autism).

54. Heidi J. Larson et al., *Addressing the Vaccine Confidence Gap*, 378 LANCET 526, 529–30 (2011) (summarizing the studies that have shown no causal connection between the use of thimerosal and autism or a connection between the measles, mumps, and rubella (MMR) vaccine and autism); *see also* INST. OF MED. (IOM), IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 7 (2004) [hereinafter IOM IMMUNIZATION SAFETY REVIEW] (discussing the misconceptions surrounding vaccinations); Maldonado, *supra* note 32, at 3156.

55. Philip J. Smith et al., *Association Between Health Care Providers' Influence on Parents Who Have Concerns About Vaccine Safety and Vaccination Coverage*, 118 PEDIATRICS e1287, e1291 (2006).

56. "Autism is a complex and severe set of developmental disorders characterized by sustained impairments in social interaction, impairments in verbal and non-verbal communication, and stereotypically restricted or repetitive patterns of behavior and interests." IOM IMMUNIZATION SAFETY REVIEW, *supra* note 54, at 32. Its etiology (causation) is uncertain and multifaceted, although there appears to be a strong genetic component. Autism has been diagnosed with greater frequency over the last several decades, although it is not clear whether this apparent increased incidence is due in part to broader diagnostic criteria and increased numbers of health and psychological professionals prepared to assist children with autism and autism spectrum disorder. Neal A. Halsey et al., *Measles-Mumps-Rubella Vaccine and Autistic Spectrum Disorder: Report from the New Challenges in Childhood Immunizations Conference Convened in Oak Brook, Illinois, June 12-13, 2000*, 107 PEDIATRICS e84, 1, 3–8 (2001). Recent research also points to fathers' genetic contribution to their children's autism. *See, e.g.*, Benedict Carey, *Study Finds Risk of Autism Linked to Older Fathers*, N.Y. TIMES, Aug. 23, 2012, at A1; Judith Shulevitz, *Why Fathers Really Matter*, N.Y. TIMES, Sept. 9, 2012, at SR 1.

57. The DPT vaccine provides protection against diphtheria, pertussis, and tetanus. The DTaP vaccine provides protection against the same diseases, but because it contains acellular (i.e., purified, cell-less pertussis) it is less likely to cause either

However, since 2001 thimerosal has not been used in any vaccine routinely administered to children under six.[58] Thimerosal is still used in the influenza vaccine, which is developed and administered annually to meet each season's new strain of influenza.[59] Other objections to mandatory vaccination are based on the fact that some vaccines contain the preservatives formaldehyde and aluminum, which are known toxins.[60] Some parents have opted out of vaccination for their children, permitting these children to act as "free riders," who are protected by their broader community's herd immunity.[61] Parental fears are promoted by Internet Web sites that provide misinformation and spread alarmist theories about the causes of autism and other childhood diseases.[62] These fears are also fed by political candidates like Michelle Bachman, who disseminate dubious claims of vaccine-related harm.[63] Even though these claims are scientifically unfounded, they receive considerable media attention. As a result, the claims are likely to take hold in the public consciousness and depress vaccination rates.[64]

The fears American parents have about vaccines reflect a confluence of factors. First, Americans have fewer children and give birth to them later than in past decades; they generally expect that the children they do have will survive to attain a healthy adulthood. It is no longer part of our collective consciousness that children will die or develop debilitating diseases and parents want to do everything possible to minimize the risk that this could occur.[65] As noted, in the 1950s, the risk of a child dying from an epidemic disease was alarmingly real;

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mild or more severe reactions in children who are inoculated. DTaP has totally replaced inoculation with DPT in the United States. IOM IMMUNIZATION SAFETY REVIEW, *supra* note 54, at 5–6; *see also* Larson, *supra* note 54; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 220–22 (both discussing the correlation between thimerosal and autism).

58. *See supra* note 57.

59. IOM IMMUNIZATION SAFETY REVIEW, *supra* note 54, at 185; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 159, B-19.

60. Sandra J. Bean, *Emerging and Continuing Trends in Vaccine Opposition Website Content*, 29 VACCINE 1874, 1877 (2011); CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 27, at 46.

61. Wendy E. Parmet, *Informed Consent and Public Health: Are They Compatible When It Comes to Vaccines?*, 8 J. HEALTH CARE. L. & POL'Y 71, 89–90 (2005).

62. Robert M. Wolfe et al., *Content and Design Attributes of Antivaccination Web Sites*, 287 JAMA 3245 (2002).

63. McCullough, *supra* note 17.

64. Grady, *supra* note 40.

65. It is probably not an accident that the logo for the National Vaccine Information Center (NVIC), one of the leading anti-vaccine groups, represents a stylized mother comforting (or protecting) a child held in her arms. *See* Nat'l Vaccine Info. Center, http://www.nvic.org (last visited Oct. 7, 2011).

today, that threat has almost disappeared.[66] For nine of the thirteen diseases preventable by vaccination, death rates have fallen by more than ninety percent from their twentieth century height. Indeed, the risk of dying from smallpox, diphtheria, and polio has been completely eliminated in the United States.[67] American life expectancy rates have never been higher.[68] Today the leading causes of death for infants are congenital anomalies, preterm delivery, Sudden Infant Death Syndrome (SIDS), and the complications of the mother's pregnancy.[69] For older children, accidents (related primarily to guns, motor vehicles, and play) are the largest single cause of death, followed by homicide, cancer, suicide, and congenital anomalies.[70] As a result of living in an era in which serious illness or death of a child is not the norm, parents are much more likely to look for a villain, a remedy, or both when death or illness does occur. Lawrence Friedman has illuminated this point in his book *Total Justice*. He argues that the twentieth century's medical and technological successes fueled Americans' rising expectations that all accident or misfortunes that are not the victim's fault must have a remedy, frequently a legal one.[71] In the case of vaccines, it is therefore expected that the rising incidence of previously rare conditions like autism has spurred some parents to look for a simple and apparently straightforward explanation, even when it is not supported by reliable scientific research.[72]

Second, we are living at a time of great uncertainty and anxiety. This is fertile ground for the development of what Richard Hofstadter called "the paranoid style in American politics," an apocalyptic belief that our nation is under siege from a vast and powerful conspiracy that threatens physical harm to our citizens, as well as the even more

66. Donald G. McNeil Jr., *Sharp Drop Seen in Deaths From Ills Fought by Vaccine*, N.Y. TIMES, Nov. 14, 2007, at A18.

67. *Id.* For four diseases—hepatitis A and B, invasive pneumococcal disease, and varicella (chicken pox)—the decline was less than ninety percent, but these vaccines were developed only recently.

68. A baby born in 2010 can expect to live 78.7 years, the longest life expectancy for American children ever projected. Nat'l Ctr. for Health Statistics, CTRS. FOR DISEASE CONTROL & PREVENTION, *Health, United States, 2012—With Special Features on Emergency Care* 77, Table 18 (2013), http://www.cdc.gov/nchs/data/hus/hus12.pdf.

69. Kenneth D. Kochanek et al., *Deaths: Preliminary Data for 2009*, 59 (#4) NATIONAL VITAL STATISTICS REPORTS 6 (Mar. 16, 2011), *available at* http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_04.pdf.

70. *Id.* at 29–30.

71. LAWRENCE M. FRIEDMAN, TOTAL JUSTICE (1994).

72. Larson, *supra* note 54, at 529. Parents' willingness to accept simplistic explanations is of course enhanced both by general societal anxiety and the Internet's "democratization" of information and expertise, discussed in the next two paragraphs.

insidious destruction of our way of life (a capitalist democracy).[73] Whether it is fear of homegrown terrorism, a vociferous debate about gun control, or a concern about a sluggish economy, a broad swath of Americans suffer from a deep sense of unease.[74] Concern over the economy has become a central preoccupation of many Americans since the global debt crisis began in 2008 and has led to a general state of anxiety.[75] Many Americans have become more fearful and less trusting in all aspects of their lives,[76] rendering them highly susceptible to the sensational claims of anti-vaccination activists.[77]

Third, ours is the age of information overload, shaped by the Internet and the lack of effective means of screening and evaluating the truth of statements presented as scientific fact, even among those who are generally well-educated.[78] This makes it easy, as well as attractive, to question authority, be it legal, medical, or scientific.[79] At the same time, recent years have witnessed a significant decline in the numbers of scientifically trained journalists.[80] Further, many jour-

73. RICHARD A. HOFSTADTER, THE PARANOID STYLE IN AMERICAN POLITICS AND OTHER ESSAYS 1, 7–9, 29 (1965).

74. *See, e.g.*, Stephen Heuser, *Risk and The City; Urban Life Means Vulnerability. That's Why We Live Here,* BOS. GLOBE, Apr. 21, 2013, at K1; Eric Schmitt & Michael S. Schmidt, *Suspects Seemed Set for Attacks Beyond Boston*, N.Y. TIMES, Apr. 22, 2013, at A1; Jonathan Weisman, *Gun Control Drive Blocked in Senate; Obama, in Defeat, Sees 'Shameful Day,'* N.Y. TIMES, Apr. 18, 2013, at A1. The Occupy Wall Street movement demonstrated that unhappiness over the American economic and political system falls along a broad ideological spectrum. Noreen Malone, *Occupying Wall Street with Yoga, Pillow Fights, and Small-Group Discussions*, N.Y. MAG., Sept. 16, 2011, *available at* http://nymag.com/daily/intel/2011/09/will_occupy_wall_street_accomp.html (last visited Nov. 1, 2011).

75. Malone, *supra* note 74.

76. *See, e.g.*, Jeff Zeleny & Megan Thee-Brenan, *New Poll Finds a Deep Distrust of Government,* N.Y. TIMES, Oct. 26, 2011, at A1; PEW RES. CENTER, *Distrust, Anger, and Partisan Rancor: The People and Their Government* (Apr. 18, 2010), http://www.people-press.org/files/legacy-pdf/606.pdf [hereinafter *Partisan Rancor*].

77. The claim by Barbara Loe Fisher is typical. *See* Fisher, *supra* note 2.

78. *Cf.* Neal Gabler, *The Elusive Big Idea*, N.Y. TIMES, Aug. 14, 2011, Sunday Review at 1.

79. *See, e.g.*, CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (2005).

80. Geoff Brumfiel, *Supplanting the Old Media?*, 458 NATURE 274 (Mar. 19, 2009); *see* MNOOKIN, *supra* note 15, at 84–86; *see also* Curtis Brainard, *CNN Cuts Entire Science, Tech Team,* OBSERVATORY (Dec. 4, 2008, 6:30 AM), http://www.cjr.org/the_observatory/cnn_cuts_entire_science_tech_t.php?page=all (last visited Oct. 26, 2011) (reporting that CNN announced it will cut its entire science, technology, and environment news staff); *see also* Taylor Mills Thomas, *How Digital Platforms Are Changing the Way Science Reporters Find and Tell Stories*, POYNTER.ORG, July 6, 2013, http://www.poynter.org/latest-news/top-stories/215405/how-digital-platforms-are-changing-the-way-science-reporters-find-tell-stories/; Curtis Brainard, *Science Journalism's Great Divide*, COLUM. JOURNALISM REV. (Jan. 21, 2013), http://www.cjr.org/the_observatory/future_of_science_journalism_w.php?page=all.

nalists appear to have embraced the mantra of "even-handedness," in which they present as equally valid anecdotes, the opinions of celebrity anti-vaccine advocates and peer-reviewed research by reputable scientists.[81] It is thus unsurprising that many Americans distrust government, corporations, physicians, and scientists.[82] This distrust, in turn, is highly correlated with perception of greater hazards: those who lack trust in expert authority are more likely to find activities to be risky than those who tend to trust in authority.[83] In the case of vaccines, all three factors combine together to make parents with serious concerns about their children's health more likely to question governmental and medical authority as they search for a remedy (and compensation) for their children's illness.[84]

The HPV Vaccine raises special concerns, not only because it protects against a sexually transmitted disease, which some people believe could be avoided by having "safe sex," but also because, so far, the vaccine has only been mandated for girls. In fact, the HPV vaccine protects against a deadly disease that causes nearly 6000 deaths annually among both men and women.[85] It is difficult to imagine any other threat to the public health that claimed several thousand American lives annually that would not provoke a robust response by both government and private organizations.[86] Although the Food and Drug Administration currently approves the vaccine Gardasil® for

81. *See* Shawn L. Otto, *America's Science Problem*, SCI. AM. 62, 71 (Nov. 2012) (describing the tendency of journalists to present "both sides" of an issue without attempting to verify the scientific support for each side); MNOOKIN, *supra* note 15, at 306 (noting concerns about celebrity activists); David Folkenflik, *McCarthy's Vaccination Stance Complicates Job on 'The View,'* NPR (July 16, 2013), *http://www.npr.org/2013/07/16/202729420/jenny-mccarthy-a-controversial-choice-for-next-view-co-host* (also noting concerns about celebrity activists); Larson, *supra* note 54, at 529; Gregory A. Poland & Robert M. Jacobson, *The Age-Old Struggle Against the Antivaccinationists*, 364 NEW ENG. J. MED. 97, 97 (2011).

82. *Partisan Rancor*, *supra* note 76; Daniel T. Willingham, *Trust Me, I'm a Scientist: Why So Many People Choose Not to Believe What Scientists Say*, SCI. AM., May 5, 2011, *available at* http://www.scientificamerican.com/article.cfm?id=trust-me-im-a-scientist.

83. PAUL SLOVIC, THE PERCEPTION OF RISK xxxiv-xxxv (2000). Gender and race also appear to affect people's perceptions of risk. *Id.* at xxxiv. Women and nonwhite males are more likely than white males to perceive risk in a given potential hazard. "Indeed, risk perceptions seem to be related to individuals' power to influence decisions about the use of hazards." *Id.*

84. *Cf.* Willingham, *supra* note 82.

85. *See supra* notes 26–29.

86. The recent surge in the debate over gun violence is the latest example of a public health issue that has captured the attention of government, private organizations, and the media, particularly when the victims are seen as innocent middle class (and largely white) children. *See, e.g.*, Bassam Gergi & Ali Breland, *The Forgotten Victims of Gun Violence*, CNN (Dec. 26, 2012, 9:37 PM), http://www.cnn.com/2012/12/26/opinion/breland-gergi-gun-victims (noting the disparate treatment of inner city and suburban gun violence).

both males and females aged nine to twenty-six, in 2006, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC), whose recommendations are generally followed by the states,[87] recommended that it be mandated only for girls, not boys.[88] This was changed in October 2011 when ACIP recommended that boys be vaccinated as well, beginning at age eleven, with catch-up vaccination for boys and young men up to age twenty-one.[89] The American Academy of Pediatrics currently recommends the vaccine for eleven to twelve-year-old adolescents of both genders.[90]

Due to the vigorous opposition of a vocal minority to mandatory HPV vaccination, only Virginia and the District of Columbia currently require HPV vaccination as a prerequisite for sixth grade girls to attend school.[91] Even in these two jurisdictions, parents are permitted to opt out of the mandate under a broader exemption than is permitted for other childhood vaccinations.[92] The rates of immunization against HPV are significantly lower than the rates for other mandatory adolescent vaccinations, both nationally and in Virginia and the District of Columbia; however, requiring immunization against HPV, as with all vaccines, increases overall vaccination rates.[93] In addition, many state legislatures have authorized public education programs about the HPV vaccination, and the federal and

87. Note, *Toward a Twenty-First Century* Jacobson v. Massachusetts, 121 HARV. L. REV. 1820, 1828–29 (2008) [hereinafter *Toward a Twenty-First Century* Jacobson].

88. Markowitz, *supra* note 5, at 1. The FDA has approved the bivalent vaccine Cervarix® for females only, aged nine to twenty-five. *Fact Sheet*, *supra* note 36.

89. Harris, *supra* note 3; *see also* Anahad O'Connor, *Officials Recommend the HPV Vaccine for All Boys*, N.Y. TIMES, Feb. 3, 2012, at A15 (describing CDC's endorsement of the ACIP recommendation, reflected in a new immunization schedule published in the Annals of Internal Medicine).

90. *HPV Vaccine Recommendations*, *supra* note 23.

91. VA. CODE § 32.1-46 (2011); D.C. CODE § 7-1651.04(b)(1) (2010). Indeed, while Virginia mandates the HPV vaccination, it is the only vaccination for which the state requires no documentation either of vaccination or exemption. VA. DEP'T OF HEALTH, *Supplemental Guidance for School-Required Vaccines* (Aug. 2013), http://www.vdh.virginia.gov/epidemiology/Immunization/documents/SchoolRegulations/SupplementalGuidance.pdf.

92. VA. CODE § 32.1-46 (2011); D.C. CODE § 7-1651.04(b)(1) (2010). In contrast, both D.C. and Virginia provide a general exemption based on the child's medical condition or religious beliefs for all other vaccinations. D.C. CODE §38-506; VA. CODE ANN. § 32.1-46(D)(1) (West 2012).

93. Centers for Disease Control, *National and State Vaccination Coverage Among Adolescents Aged 13 Through 17 Years—United States, 2010*, 60 MORBIDITY & MORTALITY WKLY. REP. (MMWR) 1117, 1121–22 (2011), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a1.htm. Nationwide, 68% of adolescents had been immunized for tetanus, diphtheria, and pertussis (via the Tdap vaccine) after the age of ten, while 81% had been immunized only for tetanus and diphtheria. More than 62% had been immunized against meningitis. In contrast, only 48% of girls had received any vaccination against HPV, while 32% of girls had received all three required HPV immunizations. *Id.*

state governments have provided funding to ensure that low-income girls can be immunized against HPV.[94] Seven states require private insurers to cover HPV vaccination.[95]

II. THE LEGAL FRAMEWORK FOR VACCINATION

A. The Public Health Perspective: Vaccination Is a Public Good

1. Substantive Due Process Requirements

Vaccination has long been regarded as a "public good," that is, a cost-effective means of addressing a shared problem that benefits everyone in society, even those who do not pay for it.[96] A century ago, in *Jacobson v. Massachusetts*,[97] the Supreme Court acted upon this understanding of "public good" when it upheld Massachusetts's authority to mandate vaccination of adults for smallpox.[98] At the time, smallpox was a dreaded disease, one which killed nearly one-third of those who contracted it.[99] A major outbreak in Boston between 1901 and 1903 had caused 270 deaths.[100] Because of smallpox's manifest threat to the community's health, the Supreme Court had no trouble in finding that mandatory vaccination was a valid exercise of a state's police power. The Court treated the Massachusetts vaccination mandate "as a matter of self-defense,"[101] reflecting the Court's understanding of the Constitution as a social compact that required sacrifice on the part of all citizens for the common good.[102] Justice Harlan drew a direct

94. NAT'L CONF. OF ST. LEGISLATURES, *HPV Vaccine* (June 2013), http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx.

95. *Id.* These states are: Oregon, Iowa, Colorado, Illinois, Maine (through state program only), Nevada, and Rhode Island.

96. *See, e.g.*, FINANCING VACCINES, *supra* note 27, at 42–44; Mark A. Hall, *The Scope and Limits of Public Health Law*, 46 (# 3 Supp.) PERSP. IN BIOLOGY & MED. S199, S204-05 (Summer 2003). In this context, the concept of "payment" refers not to compensating a health care provider who inoculates a patient but to every patient's small but real risk of suffering an adverse effect from the vaccination. Vaccination functions as a public good because of its ability to confer herd immunity on the nonvaccinated and to avoid the necessity of spending large sums of public and private money in the event of a disease outbreak. *See supra* text accompanying notes 18–19.

97. 197 U.S. 11 (1905).

98. *Id.* at 24–30. Under Massachusetts law, each local board of health was empowered to authorize mandatory smallpox vaccination for nonvaccinated adults in case of a local outbreak of the disease. *Id.* at 27.

99. *Cf.* WILLIAM FOEGE, HOUSE ON FIRE: THE FIGHT TO ERADICATE SMALLPOX (2011) (citing fatality rates of 20–40% depending on locality).

100. Lawrence O. Gostin, Jacobson v. Massachusetts *at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 577 (2005).

101. The Court declared, "Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." 197 U.S. at 27.

102. *Id.* at 27–29.

analogy between the obligation to be vaccinated and the requirement of military service, as both were necessary to the community's survival.[103] Writing in blunt, unequivocal language, he asserted:

> [T]he liberty secured by the Constitution . . . to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. *There are manifold restraints to which every person is necessarily subject for the common good.* On any other basis organized society could not exist . . . [but would dissolve into anarchy]. . . . [I]n every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.[104]

This passage illuminates four key elements of the *Jacobson* holding. Transposed to the twentieth century by public health law scholars Lawrence Gostin and James Hodge, *Jacobson* requires that in order for a vaccination mandate to pass constitutional muster as an exercise of state police power, trumping individual liberty interests, there must be "necessity . . .; reasonable means . . .; proportionality . . .; and harm avoidance."[105]

Early state and federal court cases were decided in accord with *Jacobson*, upholding laws mandating vaccination as a condition for school entry.[106] In an age that preceded the development of antibiotics, in which smallpox and other disease epidemics routinely swept through large cities, mandatory vaccination laws were seen as essential to protecting public and individual health and, therefore, justified by both police power and *parens patriae* rationales. By the early 1980s, every state had enacted laws mandating vaccinations for children prior to their entering school.[107]

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103. *Id.* at 29–30.

104. *Id.* at 26–29 (emphasis added). The court also held that it was constitutionally permissible to vaccinate Jacobson because he had not shown that he was at risk of serious harm from vaccination. The court read into the Massachusetts statute an exception from the vaccination law based on individual medical circumstances. *Id.* at 39.

105. James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 856–67 (2001–02) (explicating how *Jacobson* demonstrated these four requirements).

106. Indeed, *Jacobson* relied on state law cases, such as Viemeister v. White, 72 N.E. 97 (N.Y. 1904), which had upheld the right of the state to require evidence of vaccination before admitting children to school. *Jacobson*, 197 U.S. at 33–34. In 1922, the Supreme Court effectively upheld the authority of the city of San Antonio, Texas, to require that children be vaccinated prior to school entry in Zucht v. King, 260 U.S. 174 (1922). The Court's opinion noting that compulsory vaccination laws have long been held to be constitutional was only dicta because its actual decision was to decline jurisdiction on the ground that "it appears that the constitutional question is not . . . substantial in character." *Id.* at 176–77.

107. Malone & Hinman, *supra* note 27, at 270.

Current laws mandating vaccination[108] reflect the principle that vaccination is a public good, as well as a matter of public necessity under *Jacobson*. School-based mandates for diseases such as smallpox, polio, measles, and varicella (chicken pox) are predicated on the idea that school-age children are most at risk for these diseases because the classroom and school yard provide an ideal site for disease transmission.[109] Requiring vaccination of children prior to entering school, particularly when they attend day care, is also an essential means of protecting those who are at risk of contracting diseases even though they do not attend school: adults, children too young to attend school, and fetuses (who can suffer serious harm if they are exposed to certain diseases in utero, such as rubella and mumps).[110] However, these mandates do not distinguish among diseases based on their mode of transmission. The vaccine against tetanus, for example, protects children and adults from an infectious, but not contagious, disease; it has long been part of the normal armament against childhood diseases.[111] Two of the newest vaccines—for Hepatitis B and HPV—provide immunities against diseases, including cancer, which could, in theory, be avoided by taking certain precautions but, for reasons discussed later, require immunization as a matter of "practical necessity."[112]

Most vaccines are extremely cost-effective, saving not only lives but also millions of dollars by preventing health care expenditures for individual medical treatment as well as public health surveillance in the event of a disease outbreak.[113] For example, the DTaP vaccine,

108. Mandatory immunization laws have been enacted by each state, as well as the District of Columbia. For information about each state's current immunization requirements, see *State Information: State Mandates on Immunization and Vaccine-Preventable Diseases*, IMMUNIZATION ACTION COALITION, http://www.immunize.org/laws/ (last visited May 7, 2012) [hereinafter *State Information*].

109. Malone & Hinman, *supra* note 27, at 271.

110. Saad B. Omer et al., *Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases*, 360 N. ENG. J. MED. 1981, 1981 (2009). Even with mandates that children must be vaccinated before attending day care or school, many very young children are not immunized. Less than seventy-five percent of two-year-olds have received all of their age-appropriate immunizations. FINANCING VACCINES, *supra* note 27, at 6, 23.

111. Tetanus is a bacterium that enters the body through a wound. For children, tetanus toxoid is usually given as part of the DTaP or Tdap immunizations, which also protect against diphtheria and pertussis. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 292–98.

112. *Toward a Twenty-First Century* Jacobson, *supra* note 87, at 1820; *see* discussion *infra* Part III.

113. FINANCING VACCINES, *supra* note 27, at 46 (noting the $150 million costs of providing direct medical care to patients affected by the 1989–91 measles outbreak, as well as 130 deaths, 11,000 hospitalizations, and 55,000 cases of measles); Sanny Y. Chen et al., *Health Care-Associated Measles Outbreak in the United States After an Importation: Challenges and Economic Impact*, 203 J. INFECTIOUS DISEASES 1517, 1523–24 (2011) (documenting the nearly $800,000 cost of contain-

which protects against infection with diphtheria, tetanus, and pertussis, is extremely cost effective, saving $27.00 for every dollar spent on vaccination.[114] Immunizing newborns for Hepatitis B saves nearly $15.00 for every dollar spent on vaccination, while the varicella vaccine, which provides protection against chicken pox, saves about $5.50 for every dollar expended.[115]

In addition to the obviously coercive effect of laws that require immunization prior to entry into school or daycare, mandatory immunization laws have a normative force and, therefore, a deterrent effect, which shapes parental behavior.[116] Studies have shown that states that mandate immunization with vaccines newly approved by the Centers for Disease Control have a lower incidence of those diseases than states that do not.[117] In addition, states that strictly enforce existing vaccination laws have a lower disease incidence than those states that have taken a more relaxed approach to enforcement.[118]

2. *Is There Room for Parents to Opt Out?*

Yet a purely reflexive reliance on *Jacobson* and police power authority for mandatory vaccination may no longer be sufficient in view of some parents' concerns about vaccine safety, even if these worries are not well-grounded scientifically. No parents wish to sacrifice their children on the altar of "the common good." Current views of the Fourteenth Amendment are very different than those that prevailed at the beginning of the twentieth century. Today, most lay people, as well as legal scholars, view the Constitution as affording much more rigorous substantive and procedural due process protections of personal liberty, including autonomous medical decision-making, than it did a hundred years ago.[119] The development of a robust law of

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ing a measles outbreak in 2008, involving fourteen patients (who were unvaccinated), two hospitals, and thousands of health care workers whose immunization status had to be verified).

114. FINANCING VACCINES, *supra* note 27, at 27–28.

115. *Id.* at 28. It is possible that as newer vaccines are developed they will not be as cost-effective if the diseases against which they protect are less deadly or not widespread. *Toward a Twenty-First Century* Jacobson, *supra* note 87, at 1840.

116. Parmet, *supra* note 61, at 83–84.

117. Calandrillo, *supra* note 44, at 382. For discussion of the Centers for Disease vaccine approval process, see *infra* subsection B.1.a. In addition, when the CDC recommends routine vaccination, and states mandate it, insurance companies are more likely to include the vaccine within its coverage. *See* Jason L. Schwartz, *HPV Vaccination's Second Act: Promotion, Competition, and Compulsion,* 100 AM. J. PUB. HEALTH 1841, 1843 (2010).

118. Malone & Hinman, *supra* note 27, at 269–70. *See also* Daniel A. Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles,* 281 JAMA 47 (1999) (concluding that disease rates are higher where exemption rates are higher).

119. *See, e.g.*, Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 278 (1990) (declaring that "[t]he principle that a competent person has a constitutionally protected lib-

bioethics, which draws on both Fourteenth Amendment due process and the common law concept of informed consent, is one result.[120] In addition, courts have recognized heightened First Amendment protections for making medical decisions in the vaccination context, based on both "free exercise" and "establishment clause" doctrine.[121] The question raised by many anti-vaccine activists, as well as parents who are uncertain about the risk-benefit calculus involved in vaccinating their children, is whether parents should have a right to opt out of vaccination, either from vaccination as a whole or from vaccines to prevent particular diseases.[122]

All states permit exemptions for medical reasons.[123] Forty-eight states allow religious exemptions from vaccination requirements,[124]

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erty interest in refusing unwanted medical treatment may be inferred from our prior decisions"). A noted exception to the robust right of personal decision-making is evident, however, in regard to women's access to abortion and other reproductive rights. *See, e.g.*, Gonzales v. Carhart, 550 U.S. 124 (2007); Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992); *In re* A.C., 573 A.2d 1235 (D.C. 1990); Pemberton v. Tallahassee Mem'l Reg'l Med. Cent., Inc., 66 F. Supp. 2d 1247 (N.D. Fla. 1999) (dismissing plaintiff's § 1983 action against a Florida hospital that obtained a court order to compel her to submit to a Caesarian section over her objections).

120. The place of informed consent in a mandatory vaccination scheme will be explored in more detail in section II.C., *infra*.

121. *See infra* text accompanying notes 128–34.

122. Vaccination is not risk free. Many children have minor reactions to vaccination and a relatively small number of children have more serious ones, as are reflected in the approximately 10,000 "adverse events" reported annually to the Vaccine Adverse Effect Reporting System. *See* discussion *infra* notes 141–43. However, the relative risk of injury from vaccination compared to not being vaccinated is extremely small. The question raised by parental opt outs is whether parents who chose not to have their children vaccinated are essentially "free riders," who depend on other children being vaccinated to reduce their own child's chance of developing a vaccine-preventable disease. Parmet, *supra* note 61, at 89–90.

123. Every state has statutory and/or administrative mandates for immunization against common childhood diseases. *See, e.g.*, *State Information*, *supra* note 108. As noted above, the *Jacobson* court implied a medical exemption into the Massachusetts mandatory vaccination law. Jacobsen v. Massachusetts, 197 U.S. 11, 39 (1905). Patients can receive a medical exemption from vaccination if they provide documentation that they are immunocompromised, have had allergic reactions to vaccination in the past, or have a moderate or severe illness. Salmon, *supra* note 118, at 47–48.

124. Malone & Hinman, *supra* note 27, at 273–74. *See also* Daniel R. Feikin et al., *Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization*, 284 JAMA 3145, 3145 (2000) (discussing the distribution of immunization exemptions amongst states); NAT'L CONF. ST. LEGISLATURES, *States with Religious and Philosophical Exemptions from School Immunization Requirements* (Dec. 2012) [hereinafter NAT'L CONF.], http://www.ncsl.org/issues-research/health/school-immunization-exemption-state-laws.aspx (collecting the works of state legislatures generally); INST. FOR VACCINE SAFETY, *Vaccine Exemptions*, http://www.vaccinesafety.edu/cc-exem.htm (last updated Feb. 12, 2014) (breaking down exemptions by state and exemption type). The Child Abuse Prevention and Treatment Act of 1974, 42 U.S.C. § 5101, which provided

and nineteen states authorize parents to seek exemption for "philosophical" reasons.[125] In those states in which it is relatively easy to obtain an exemption from vaccination,[126] a greater percentage of parents opt out.[127]

In the last fifty years, there has been substantial litigation over the scope and constitutionality of state laws that provide religious exemptions from childhood vaccination requirements. Some writers have suggested that states have *no* constitutional obligation to enact such an exemption,[128] relying on *Prince v. Massachusetts*,[129] a case from the 1940s in which an adult's religious beliefs clashed with child labor laws. In *Prince* the Court observed in dicta, "The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."[130]

However, in more recent years many states' religious exemption laws have been challenged on the ground that the exemptions are too restrictive. Most suits have been successful. Some parents have challenged state religious exemption laws because they limit exemption to those who are members of a religious group with tenets opposing vaccination or members of a "nationally recognized church," thus arguably running afoul of the Establishment Clause or the Equal Protection Clause of the Fourteenth Amendment.[131] Other suits have asserted

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federal funding to states that adopted policies consistent with its requirements, led to the expansion of religious exemptions to state vaccination requirements. The Act's implementing regulations provided that parents' failure to provide medical treatment due to their religious beliefs did not, for that reason alone, constitute child abuse or neglect. Even though this law was later repealed, most states retained their exemptions. Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 282 (2003).

125. The number of states with philosophical exemptions has increased in recent years, from fifteen in the early twenty-first century to nineteen today. NAT'L CONF., *supra* note 124; INSTIT. FOR VACCINE SAFETY, *supra* note 124.

126. Silverman, *supra* note 124, at 278.

127. Malone & Hinman, *supra* note 27, at 274; *see* Salmon et al., *Parental Vaccine Refusal in Wisconsin: A Case-Control Study*, 108 (#1) WIS. MED. J. 17, 17 (2009).

128. Hodge & Gostin, *supra* note 105, at 859.

129. 321 U.S. 158 (1944) (rejecting the First Amendment free exercise of religion claim brought by a Jehovah's Witness who claimed that the state's enforcement of a child labor law to prevent her nine-year-old niece from distributing religious literature violated her right to the free exercise of religion). The case is widely cited for its grand rhetorical flourish, "Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves." *Id.* at 170.

130. *Id.* at 166–67.

131. *See, e.g.*, Sherr v. Northport-East Northport Union Free Sch. Dist., 672 F. Supp. 81, 89–90 (E.D. N.Y. 1987) (invalidating New York's religious exemption because it was limited to "bona fide members of a recognized religious organization"); McCarthy v. Boozman, 212 F. Supp. 2d 945, 949 (W.D. Ark. 2002) (similar exemp-

that once a state has authorized a religious exemption to vaccination, courts and administrative agencies should not be permitted to scrutinize the sincerity of a parent's religious beliefs.[132] In response to litigation, two state legislatures have eliminated the religious exemption completely,[133] while other states have broadened their exemptions to make them more widely available, particularly to parents whose beliefs are more idiosyncratic and less clearly tied to religious doctrine.[134]

In addition, for parents who cannot meet the requirements for religious exemption,[135] increasing numbers of states are enacting "philosophical" or "personal belief" exemptions, which permit parents to opt out of vaccination for their children on broader, more secular,

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tion). *But see* Kleid v. Bd. of Educ., 406 F. Supp. 902, 904, 906–07 (W.D. Ky. 1976) (finding that a Kentucky law limiting the exemption to "members of a nationally recognized . . . church . . . opposed to medical immunization against disease" did not violate the Establishment Clause). Subsequently, however, the Kentucky Legislature changed the law to eliminate this requirement. 1976 Ky. Acts 128, § 4.

132. *See In re* Le Page v. State of Wyo. Dep't of Health, 18 P.3d 1177, 1179–81 (Wyo. 2001) (holding, on statutory grounds alone, that a statute's provision that vaccination waivers "shall" be granted means that the state health department does not have discretionary authority to deny a parent's religiously based request for an exemption and observing in dicta that to permit state scrutiny of the merits or sincerity of the claimed religious beliefs would raise constitutional questions). *But cf.* Farina v. Bd. of Educ., 116 F. Supp. 2d 503, 513 (E.D.N.Y. 2000) (holding, after extensive scrutiny of the credibility of parents' testimony, that their proffered religious beliefs were in fact not grounded in religion, but were instead based on health concerns).

133. M. Craig Smith, *A Bad Reaction: A Look at the Arkansas General Assembly's Response to* McCarthy v. Boozman *and* Boone v. Boozman, 58 ARK. L. REV. 251, 279–80 (2005) (explaining the Mississippi Legislature's response to the decision in Brown v. Stone, 378 So. 2d 218, 223 (Miss. 1979), which invalidated Mississippi's religious exemption on the ground that it violated the Equal Protection Clause by permitting children who *were* vaccinated, but perhaps still at risk, to be exposed to children whose parents had opted out of vaccination on their behalf). The Mississippi statute currently provides no exemptions. MISS. CODE ANN. § 41-23-27 (West 1983).

134. *See, e.g.*, the relaxed Arkansas statute, providing that, "This section shall not apply if the parents or legal guardian of that child object thereto on the grounds that immunization conflicts with the religious or philosophical beliefs of the parent or guardian." ARK. CODE. ANN. § 6-18-702(4)(A) (West 1997). California has also adopted an expansive exemption provision, providing:

> Immunization of a person shall not be required for admission to a school or other institution listed in Section 120335 if the parent . . . files with the governing authority a letter or affidavit that documents . . . which immunizations have not been given on the basis that they are contrary to his or her beliefs.

CAL. HEALTH AND SAFETY CODE § 120365 (2013).

135. *See, e.g.*, Hanzel v. Arter, 625 F. Supp. 1259, 1260, 1265–66 (S.D. Ohio 1985) (rejecting an equal protection clause challenge to the Ohio religious exemption because it did not allow exemption based on the plaintiffs' belief in "'chiropractic ethics'").

grounds.[136] While proponents of these laws claim that they support the parental interest in making medical decisions for their children, others charge that enacting less stringent opt-out laws will jeopardize the health of the entire community.[137]

Today, rates of immunization for several diseases have declined nationwide,[138] a trend which may reflect states' adoption of more generous exemption policies,[139] as well as the growing parental embrace of "alternative vaccination schedules," contrary to those recommended by the Centers for Disease Control and the American Academy of Pediatrics.[140] Studies have found that as many as a fifth of all parents of young children have adopted alternative vaccination schedules, skipping vaccinations for certain diseases altogether, or delaying and "spreading out" recommended vaccines.[141] Of these parents, less than

136. Silverman, *supra* note 124, at 284–85. *See, e.g.*, the Arizona statute, enacted in 2007, which provides:

> A. Documentary proof is not required for a pupil to be admitted to school if one of the following occurs: 1. The parent or guardian of the pupil submits a signed statement to the school administrator stating that the parent or guardian has received information about immunizations provided by the department of health services and understands the risks and benefits of immunizations and the potential risks of nonimmunization and that due to personal beliefs, the parent or guardian does not consent to the immunization of the pupil.

Ariz. Rev. Stat. § 15-873 (2007).

137. Hodge & Gostin, *supra* note 105, at 883–84; Silverman, *supra* note 124, at 284–85, 293–94. Whether the exemption is religious or philosophical, some states provide perverse incentives for school districts to enforce mandatory vaccination laws. For example, in Washington State, schools are penalized financially when they fail to have documentation that a student is either completely vaccinated or is exempt; in practice, this may lead some school principals to encourage parents whose children are not fully immunized to claim an exemption. Calandrillo, *supra* note 44, at 360–61, 436; *see also* Bruce Jancin, *Exemptions to Mandatory School Immunization Laws Climbing*, 36 (8) PEDIATRIC NEWS 12 (Aug. 2002). In contrast, in New York state, school districts actively challenge the granting of any religious exemption. Calandrillo, *supra* note 44, at 418. In New York City, principals are fined $2,000 a day for each unvaccinated child. Donald G. McNeil Jr., *Worship Optional, Joining a Church to Avoid Vaccines*, N.Y. TIMES, Jan. 14, 2003, at F1; *see also* N.Y.C. PUB. HEALTH CODE § 2164 (allowing an exemption for children whose parents hold sincere religious beliefs opposing vaccination).

138. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at G-8.

139. Saad B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 JAMA 1757, 1761 (2006).

140. Amanda F. Dempsey et al., *Alternative Vaccination Schedule Preferences Among Parents of Young Children*, 128 PEDIATRICS 848, *available at* http://pediatrics.aappublications.org/content/128/5/848.full.pdf+html?sid=2e751729-1f83-4ae5-abb4-7f8d94094ea5.

141. KJ Dell'Antonia, *The A.A.P. Has a New Vaccine Schedule. Will You Follow It?*, N.Y. TIMES (Jan. 29, 2013, 1:53 PM), http://parenting.blogs.nytimes.com/2013/01/29/theres-a-new-vaccine-schedule-will-you-follow-it/?_r=0; Dempsey, *supra* note 140; *see also* ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS, COMMUNICATING

ten percent followed a widely publicized alternative schedule; instead, more than fifty percent devised the schedule themselves or with the help of a friend.[142] Because older children must be vaccinated (or exempted) in order to attend school or day care, the practical result of these parental actions is that younger children (as well as others who cannot be vaccinated for medical reasons) are at greater risk for contracting these diseases.[143]

Similarly, in states whose exemption laws make it easier to opt out of vaccination, exemption rates are higher and have risen more rapidly than those states where the process of obtaining an exemption is more arduous.[144] States that grant religious and philosophical exemptions have higher exemption rates than those that authorize exemption only on religious grounds.[145] In turn, states where exemption is more common have an increased incidence of pertussis and measles compared with states where exemption is harder to obtain.[146]

Even when overall rates of vaccination remain relatively high, in communities where many parents opt out of vaccination the rates of immunization have been much lower. For example, when the rate of exemption statewide in Washington state averaged six percent,[147] the exemption rates across counties varied from just over one percent to more than twenty-six percent.[148] Because religious and philosophical exemptions tend to cluster in particular communities, this can lead to a lack of herd immunity. Then, if a disease does enter a community, it spreads rapidly.[149] One study found that school-age children whose parents had exempted them from vaccination were thirty-five times

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EFFECTIVELY ABOUT VACCINES: NEW COMMUNICATION RESOURCES FOR HEALTH OFFICIALS 12 (Nov. 2010), *available at* http://www.astho.org/Display/AssetDisplay.aspx?id=5464 (providing information about vaccinations for parents reluctant to vaccinate their children).

142. Dempsey, *supra* note 140.

143. *See* sources cited *supra* note 19.

144. Omer, *supra* note 139, at 1758–60. Maryland is a typical "easy" opt-out state. Its exemption form provides, "Because of my bona fide religious beliefs and practices, I object to any immunizations being given to my child," and the form requires only the parent's signature. MD. DEP'T OF HEALTH & MENTAL HYGIENE, *Maryland Department of Health and Mental Hygiene Immunization Certificate* (2011), *available at* http://ideha.dhmh.md.gov/OIDEOR/IMMUN/Shared%20Documents/896_form.pdf.

145. Omer, *supra* note 139, at 1761.

146. *Id.*

147. This is much higher than the national average, which was 2.5% in 2004 for states that offered "personal belief" exemptions. Omer, *supra* note 139, at 1759.

148. *Id.*

149. *Id.*

more likely to contract measles than their vaccinated peers; younger children were at even greater risk.[150]

Two distinct demographic groups are less likely to have their children vaccinated. One is poor communities of color, in which parents are often foreign-born and sometimes illiterate, and where routine access to health care is hard to obtain.[151] The second, surprisingly, is well-educated and affluent communities. In these communities parents may be more likely to seek alternative medical approaches and believe that they are able to make a fully informed decision about the merits of vaccination based on what they read on the Internet.[152] Indeed, a recent study found that for some diseases, children whose vaccination is paid for by Medicaid are more likely to be vaccinated than children with private health care coverage, reversing the long-standing phenomenon that wealthier children receive better health care.[153]

B. Regulatory Oversight and Support

1. Federal Law

a. Safety

While some parents express concern over the safety of vaccination, the federal government is actively promoting vaccine safety on multiple fronts. In the early to mid-twentieth century there were rare, but frightening, instances in which healthy children and adults were killed or injured as a result of vaccination, primarily because the vaccines were contaminated or used live, rather than killed, viruses.[154]

150. Daniel A. Salmon et al., *supra* note 118, at 47, 49. Similar patterns have been shown for pertussis. Feikin, *supra* note 124, at 3147.

151. McNeil, *supra* note 66; Tsouderos, *supra* note 24. *See infra* section II.B. discussion (concerning government efforts to support the immunization of all children, regardless of their parents' financial resources).

152. Tsouderos, *supra* note 24; Liz Szabo, *Preventable Measles Makes a Comeback; Skipping Vaccines for Philosophical Reasons Puts Others at Risk*, USA TODAY, June 15, 2011, at 1D.

153. NAT'L COMM. FOR QUALITY ASSURANCE, THE STATE OF HEALTH CARE QUALITY 12 (2010) (noting that "[o]ne of the most striking developments in this year's *The State of Health Care Quality Report* is the contrast in performance on childhood vaccination rates between commercial and Medicaid populations. The vaccination rate declined by almost four percentage points among commercial enrollees while it actually improved by nearly three percentage points among Medicaid plan members.")

154. MNOOKIN, *supra* note 15, at 37–38, 46–54; JAMES K. COLGROVE, VACCINATION POLICY, POLITICS AND LAW IN THE TWENTIETH CENTURY 207–08 (University of California Press 2004) (describing the incident which marred the launch of the Salk polio vaccine, when more than 200 people contracted polio after receiving vaccine in which the polio virus had not been sufficiently inactivated during manufacturing). Even as late as the 1990s, every year an average of nine individuals contracted paralytic poliomyelitis as a result of vaccination. This risk was eliminated by the development of the inactivated polio virus, which has been

In 1902, Congress recognized the need for government oversight when it enacted the Virus Serums and Toxins Act. This Act gave the Food and Drug Administration (FDA) the authority to license vaccines to ensure, through animal and human studies, that they are safe and effective in preventing disease and manufactured under processes guaranteed to avoid contamination or other forms of toxicity.[155]

To assure that the vaccines it licenses are both necessary for the protection of the public health and well-designed, the FDA works closely with the Advisory Committee on Immunization Practices (ACIP), an agency of the Centers for Disease Control (CDC).[156] ACIP provides guidance concerning what new vaccines should be developed, as well as their most appropriate formulation,[157] and recommends how vaccines should be deployed (i.e., singly or in combination) once they are licensed.[158] ACIP also works with relevant professional groups, such as the American Academy of Pediatrics, to recommend vaccine administration schedules for each targeted disease, including the schedule for childhood immunizations.[159]

The CDC also collaborates with other entities to oversee vaccine safety after licensure.[160] The Vaccine Adverse Event Reporting System (VAERS) is a joint program of the CDC and the FDA, established by the National Childhood Vaccine Injury Act of 1986[161] to encourage health care providers (physicians, hospitals, etc.) to report all serious adverse health events that might be related to vaccination.[162] Data collected through VAERS is reviewed for possible patterns of injury,

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used exclusively since 2000. Lorraine Nino Alexander, *Vaccine Policy Changes and Epidemiology of Poliomyelitis in the United States*, 292 JAMA 1696, 1696–1700 (2004).

155. DEP'T OF HEALTH & HUMAN SERVS., A COMPREHENSIVE REVIEW OF FEDERAL VACCINE SAFETY PROGRAMS AND PUBLIC HEALTH ACTIVITIES 4–5, 7–16 (Dec. 2008), *available at* http://www.hhs.gov/nvpo/nvac/documents/vaccine-safety-review.pdf; Julie B. Millstein, *Regulation of Vaccines: Strengthening the Scientific Base*, 25 J. PUB. HEALTH POL'Y 173, 174–80 (2004); CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 47; FINANCING VACCINES, *supra* note 27, at 45. These processes are referred to as Good Manufacturing Practices (GMPs) and current Good Manufacturing Processes (cGMPs).

156. FINANCING VACCINES, *supra* note 27, at 57–59.

157. Jean Clare Smith, *The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices ACIP)*, 28S VACCINE A68, A71 (2010).

158. *Id.* at A68, A71; DEP'T OF HEALTH & HUMAN SERVS., *supra* note 155, at 53.

159. Smith, *supra* note 157, at A71–72. ACIP's Working Group for Harmonized Schedule for Children and Adolescents coordinates the recommendations of ACIP, the American Academy of Pediatrics, and the American Academy of Family Physicians, to annually update the schedule for childhood immunizations. Orenstein, *supra* note 26, at 1007.

160. Maldonado, *supra* note 32, at 3157.

161. *Id.*

162. Orenstein, *supra* note 26, at 1012; DEP'T OF HEALTH & HUMAN SERVS., *supra* note 155, at 18.

which are then investigated.[163] The Vaccine Safety Datalink (VSD) is a program in which the CDC routinely receives data from large managed care organizations (MCOs) on the immunization of more than 600,000 children under age seven, as well as other age groups, in order to identify any potential adverse outcomes of vaccination not discovered during the smaller clinical trials required to obtain FDA vaccine licensure.[164] A third project, the Clinical Immunization Safety Assessment Network, was established in 2001 to study suspected adverse events and give health care providers the expertise to handle individual patients' adverse reactions by providing immediate access to the CDC and regional centers for vaccine safety.[165]

Over the last decade, the federal government has convened multiple scientific panels to study vaccine safety, particularly the question of whether vaccines cause autism. These panels have repeatedly found no evidence of a causal relationship between vaccination and autism or other chronic disorders. The Institute of Medicine of the National Academies of Science convened eight separate review panels between 2001 and 2004 to address the separate allegations that vaccines containing thimerosal, a mercury-based preservative, caused autism and that the combined measles, mumps, and rubella vaccine (MMR) caused autism.[166] For each allegation, the IOM found that the "evidence favors rejection of a causal relationship" between vaccination and autism.[167] Acknowledging the concerns of families affected by autism, the IOM urged that future research should focus primarily on understanding the etiology (including the biological, environmental, and genetic bases) of autism and on developing appropriate treatments for the disease. Increasing research has shown a genetic contribution, through mutations of fathers' DNA, to some forms of autism.[168] At the same time, during the last several years, earlier research purporting to establish a link between vaccination and autism

163. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 155, at 18–23. In addition, data from other age groups within the managed care organizations' (MCO) patient bases can be analyzed for adverse health events that could be connected with vaccination so that appropriate remedial action can be taken. *Id.*; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 50–51 (explaining the process of monitoring vaccine safety); Maldonado, *supra* note 32, at 3155–57.

164. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 155, at 18–23.

165. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 51–52.

166. IOM IMMUNIZATION SAFETY REVIEW, *supra* note 54, at 2.

167. *Id.* at 1. Other researchers have reached conclusions similar to those of the IOM. *See* sources cited *supra* note 39.

168. *See, e.g.*, Jordan W. Smoller et al., *Identification of Risk Loci with Shared Effects on Five Major Psychiatric Disorders: A Genome-Wide Analysis*, 381 LANCET 1371, 1371, 1376–77 (2013), *available at* http://press.thelancet.com/psychiatricdisorders.pdf; *Study Finds Mutations That May Cause Autism*, TORONTO STAR, Apr. 5, 2012, at A26; Halsey, *supra* note 56; Carey, *supra* note 56; Shulevitz, *supra* note 56.

has been discredited or withdrawn as fraudulent and/or lacking in scientific rigor.[169]

Yet the clamor over vaccine safety continues. Ironically, it appears that efforts by government and vaccine manufacturers to enhance vaccine safety can have the opposite result. For example, when, out of an abundance of caution, the Institute of Medicine recommended that thimerosal be removed from routine childhood vaccines, this action only fueled suspicion that thimerosal *was* harmful.[170] Similarly, the mere existence of VAERS (and the number of adverse reactions reported annually) sends the message to vaccine skeptics that vaccines *are* dangerous.[171] In addition, the fact that vaccines have different formulations or are administered on somewhat different schedules in the United States and other countries can suggest that "health authorities did not exactly know which vaccine produced the best . . . formulation," leading to a decline in public confidence about

169. MNOOKIN, *supra* note 15, at 299–302; *see also* Editors, *Retraction-Ileal-Lymphid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 375 LANCET 445, 445 (2010) (retracting the 1998 Andrew Wakefield study finding a link between vaccination and autism due to the flawed science noted in the negative findings of the United Kingdom's General Medical Council's Fitness to Practice Panel on Jan. 28, 2010); Nick Triggle, *MMR Scare Doctor 'Acted Unethically,' Panel Finds*, BBC NEWS (Jan. 28, 2010), http://news.bbc.co.uk/2/hi/health/8483865.stm (explaining that the link between autism and vaccinations has been discredited because Dr. Andrew Wakefield's research was conducted dishonestly).

170. Thimerosal was added as a vaccine preservative to guard against contamination of vaccines. In the United States, such preservatives are no longer necessary because all vaccines are no longer administered from multiple dose vials; however, in much of the developing world, that is the only affordable way to provide vaccination. A 2010 study examining maternal and infant exposure to thimerosal found no evidence of a casual relationship between prenatal and infant thimerosal exposure and the development of an autism spectrum disorder. Cristofer S. Price et al., *Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism*, 126 PEDIATRICS 656, 656 (2010). This study confirms a number of earlier studies, including a 2004 Institute of Medicine review, which considered multiple studies of the effects of administering vaccines with and without thimerosal (including populations in Denmark, Sweden, the United States, and the United Kingdom) and found no credible evidence of a causal relationship between thimerosal exposure via vaccines and the incidence of autism. IOM IMMUNIZATION SAFETY REVIEW, *supra* note 54, at 65.

171. *See, e.g.*, Barbara Loe Fisher, *In the Wake of Vaccines*, MOTHERING, Sept.–Oct. 2004, at 38, 43. Fisher's faulty logic began with the assertion that "each year about 12,000 reports are made to the Vaccine Adverse Event Reporting system; parents as well as doctors can make those reports." She continued, "However, if that number represents only 10 percent of what is actually occurring, then the actual number may be 120,000 vaccine-adverse events. If doctors report vaccine reactions as infrequently as [former FDA Commissioner] Dr. [David] Kessler said they report prescription-drug reactions, and the number 12,000 is only 1 percent of the actual total, then the real number may be 1.2 million vaccine-adverse events annually." *Id.*

vaccine safety.[172] Even the fact that some physicians deviate slightly from the recommended vaccination schedule may make some parents skeptical about the necessity of vaccination—or at least vaccination on any particular timetable.[173]

Many public health officials have recently attempted to be more transparent about the risks and benefits of vaccination so that parents can make informed decisions about vaccination. There is a consensus that pediatricians and other family physicians are the most important resource for parents in making decisions about their child's vaccination and that these physicians should be more actively involved in educating parents about why vaccination is necessary and alleviating parental concerns.[174] The CDC and state public health officers are working to increase public understanding of the risks and benefits of vaccination, on both an individual and community level.[175]

b. Vaccine Development and Financing

Historically, only physicians and private (usually for-profit) research organizations were involved in vaccine development. However, the federal government has been actively involved in vaccine development since the mid-twentieth century. The federal government's research involvement began with the drive to eliminate polio, which culminated with the development of both the Sabin and Salk polio vaccines.[176] Today the federal government encourages vaccine development through the National Institute of Health's funding of basic re-

172. Steven Black & Rino Rappuoli, *A Crisis of Public Confidence in Vaccines*, SCI. TRANSLATIONAL MED., Dec. 8, 2010, at 1, 4, *available at* www.ScienceTranslationalMedicine.org.

173. For this insight, I am indebted to my colleague Emily Gold Waldman. The recommended vaccination schedule is developed jointly by ACIP, the American Academy of Pediatrics, and the American Academy of Family Physicians. *See also* Maldonado, *supra* note 32, at 3155; *see* sources cited *supra* note 141; *see also* Dell'Antonia, *supra* note 141 (examining the various arguments for and against following the recommended vaccination schedule).

174. Doren D. Fredrickson et al., *Childhood Immunization Refusal: Provider and Parent Perceptions*, 36 FAM. MED. CLINICAL RES. & METHODS 431, 433–34, 436–37 (2004).

175. CTRS. FOR DISEASE CONTROL & PREVENTION, PARENTS' GUIDE TO CHILDHOOD IMMUNIZATIONS 31–51 (2010), *available at* http://www.cdc.gov/vaccines/pubs/parents-guide/default.htm; *see also* ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS, *supra* note 141, at 13.

176. CENTERS FOR DISEASE CONTROL & PREVENTION, *supra* note 34. At the same time that the development of these two vaccines saved thousands of lives in the United States alone, in the rush to make them more available to the public, there were isolated incidents of faulty manufacturing that led to scores of polio infections and injuries. Similar concerns were raised after a relatively large (and statistically unexpected) number of people developed Guillain-Barre syndrome shortly after being vaccinated against the swine flu in 1976. Millstein, *supra* note 155, at 176, 180; MNOOKIN, *supra* note 15, at 65.

search, as well as the patent system's provision of financial incentives for research and development.[177] At the same time, other government actions may make vaccine research and development *less* attractive to industry since the government's significant economic power as a purchaser of large quantities of vaccines tends to keep prices lower.[178] This may be changing, however, as small biotech companies are discovering promising vaccines to prevent a wider array of diseases and philanthropists like Bill and Melinda Gates are proposing to fund vaccine research, which has a potential pay-off in the developing world.[179]

The federal government also directly funds the purchase of vaccines for children and adults. Since the 1920s, the government has focused on the health of poor children and their mothers through the Shepherd-Townsend Act, funding the vaccination efforts of state and local health departments.[180] Federal and state governments have made special efforts to ensure the immunization of low-income children, through Medicaid, the State Child Health Insurance Program (SCHIP), the Vaccines for Children Program, and the "317" grant program,[181] which funds purchase of vaccines by state and local health departments as well as administrative infrastructure and outreach activities to support vaccination.[182]

Under the Affordable Care Act (ACA), all childhood and adult vaccinations recommended by ACIP and the CDC must be provided by both public and private health insurance and MCOs.[183] These bene-

177. FINANCING VACCINES, *supra* note 27, at 40–41, 47.

178. *Id.* at 40–41.

179. *See, e.g.*, Belinda Beresfod & Jerald C. Sadoff, *Update on Research and Development Pipeline: Tuberculosis Vaccines*, 50 CLINICAL INFECTIOUS DISEASES (SUPP. 3) S178–83 (2010); Julie M. Donnelly, *Biotechs Find Progress in Vaccine Market*, BOS. BUS. J., Feb. 3, 2010, *available at* http://www.masshightech.com/stories/2010/02/01/weekly10-Biotechs-find-progress-in-vaccine-market.html.

180. FINANCING VACCINES, *supra* note 27, at 39.

181. The "317" program is administered by the Centers for Disease Control and is so called because it was authorized in 1962 by § 317 of the Public Health Services Act, 42 U.S.C. § 247(b). Malone & Hinman, *supra* note 27, at 268.

182. Malone & Hinman, *supra* note 27. The Vaccines for Children Program was established by Congress through the Omnibus Reconciliation and Budget Act of 1993, by adding section 1928 to the Social Security Act, 42 U.S.C. § 1396s. The Program provides free vaccines for eligible children, who are those who are either eligible for Medicaid, uninsured, underinsured, or Native American. FINANCING VACCINES, *supra* note 27, at 7–9, 16, 34, 46–47. However, it is often difficult and time-consuming for physicians to figure out which program covers a particular patient, imposing administrative burdens that decrease immunization levels overall. Forty-one percent of children's vaccine costs nationwide (both direct and indirect) are paid for by the Program. KAISER FAMILY FOUND., HPV VACCINE: IMPLEMENTATION AND FINANCING POLICY IN THE U.S. 1 (2008).

183. Shining a Light on Health Insurance Rate Increases, CENTERS FOR MEDICARE & MEDICAID SERVICES (Dec. 21, 2010), http://www.healthcare.gov/news/factsheets/2010/09/ affordable-care-act-immunization.html (noting that these requirements

fits must be provided without cost-sharing requirements (i.e., co-pays and deductibles) by private insurance organizations and with very limited cost-sharing requirements under Medicaid.[184]

2. *State Oversight of Vaccination*

a. *Mandating Immunization (and the Exemption Process)*

Each state establishes its own requirements for childhood immunization as a prerequisite to attending school and day care, although in practice most states simply follow the recommendations of ACIP.[185] As noted, every state also provides exemption from these requirements for medical reasons. Forty-eight states authorize exemption for religious reasons and twenty permit exemption based on parents' philosophical or personal beliefs.[186] Some commentators have voiced concern that rising numbers of home-schooled children will not be vaccinated because most states do not mandate childhood immunization for such children.[187]

b. *Funding or Mandating Vaccination Coverage*

As noted above, the states receive significant federal financial support to encourage childhood vaccination, through funding of infrastructure to support outreach to parents, to pay for physicians' services, as well as direct federal purchasing of vaccines through the Vaccines for Children Program.[188] While very poor children are eligible for vaccinations paid for by the federal or state government, about fourteen percent of children are underinsured; that is, they have some health care coverage under their parents' insurance plans, but the in-

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apply to those who enroll in new group or individual plans on or after Sept. 23, 2010); *see also* ALEXANDRA M. STEWART ET AL., GEORGE WASHINGTON UNIV. MED. CTR., THE AFFORDABLE CARE ACT: U.S. VACCINE POLICY AND PRACTICE iii (2010) (stating that the Affordable Care Act will ensure vaccines and immunizations for all people, regardless of health insurance coverage).

184. The no-cost-sharing rule applies to patients who receive their immunizations in-network and does not apply to "grandfathered" (i.e. existing) private health plans, although it is expected that all but the largest private employer-provided health plans will lose their grandfathered status within a few years. STEWART, *supra* note 183, at 5–6, 8, 11–13; *see also* CENTERS FOR MEDICARE & MEDICAID SERVICES, *supra* note 183 (explaining that the Affordable Care Act imposes strict regulations on insurance companies so that vaccines are readily available for everyone).

185. *See* IMMUNIZATION ACTION COALITION, *supra* note 108; Malone & Hinman, *supra* note 27, at 268.

186. *See* discussion *supra* notes 105–08; NAT'L CONFERENCE OF STATE LEGISLATURES, STATES WITH RELIGIOUS AND PHILOSOPHICAL EXEMPTIONS FROM SCHOOL IMMUNIZATION REQUIREMENTS (Feb. 2012), http://www.ncsl.org/issues-research/health/school-immunization-exemption-state-laws.aspx.

187. *See, e.g.*, Donya Kalili & Arthur Caplan, *Off the Grid: Vaccinations Among Homeschooled Children*, 35 J. L. MED. & ETHICS 471 (2007).

188. *See* discussion *supra* subsection II.B.1.

surance often does not pay for routine immunization (e.g., a "well-child" visit).[189] More than half the states mandate that health insurers in their states provide all, or a majority, of the vaccinations recommended by ACIP. However, many health insurers are not covered by these mandates due to ERISA, the Employee Retirement Income Security Act of 1974,[190] which preempts many state law mandates.[191] As noted above, under the Affordable Care Act, all children (and adults) must receive all CDC-recommended vaccinations.[192]

C. Tort Liability, Alternative Compensation Schemes, and Informed Consent

1. Tort Liability and the National Childhood Vaccine Injury Compensation Act

In the mid-1980s many vaccine manufacturers cited the mounting costs of tort liability as grounds for leaving (or threatening to leave) the vaccine market, which was already less profitable than other segments of the pharmaceutical market because of the government's significant market power as a large scale purchaser of vaccines.[193] In 1986, Congress responded by enacting the National Childhood Vaccine Injury Compensation Act (NCVICA or the Act), which enhanced federal oversight of vaccine development and safety issues[194] at the same time that it established a no-fault compensation scheme for children whose injuries were caused by vaccination.[195] As a further aspect of the trade-offs embodied in the Act, federal law preempts most types of common law actions against vaccine manufacturers.[196] Under the administrative compensation system the Act establishes,

189. Financing Vaccines, *supra* note 27, at 63–65, 86.
190. 29 U.S.C. §§ 1001–1461 (2006).
191. FINANCING VACCINES, *supra* note 27, at 72.
192. *See supra* text accompanying notes 164–65.
193. Parmet, *supra* note 61, at 87–88; *see also* Elizabeth Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 354–55 (2001) (criticizing the Act as making it too hard for cases to be adjudicated and for parents to be compensated).
194. Bruesewitz v. Wyeth, 131 S. Ct. 1068, 1079–80 (2011) (noting that the Act "directs the Secretary of Health and Human Services to promote 'the development of childhood vaccines that result in fewer and less serious adverse reactions,'" to "set priorities for federal vaccine research, and to coordinate federal vaccine safety and efficacy testing," as well as to require the reporting of adverse vaccine effects and to establish monitoring of vaccine data).
195. Mary J. Davis, *The Case Against Preemption: Vaccines and Uncertainty*, 8 IND. HEALTH L. REV. 291, 294 (2011). The Act established a compensation fund, paid for by a $.75 charge for each immunization provided. Betsey J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343, 344 (2011).
196. *Bruesewitz*, 131 S. Ct. at 1080 (discussing "the Act's structural *quid pro quo*"). The extent of that quid pro quo was at the heart of the Bruesewitz case. *See supra* note 194; *see infra* note 222.

children whose injuries are included in a table of recognized adverse reactions to a vaccine are presumed to have had those injuries caused by vaccination; compensation follows virtually automatically.[197] However, children whose injuries are not listed in the table must prove their claim by a preponderance of the evidence, establishing both general causation (a finding that the vaccine is capable of causing the particular harm alleged) and specific causation (that the vaccine did so in this child's case).[198] Hundreds of parents of children suffering from autism or an autism spectrum disorder claimed that their children's condition was caused by vaccination.[199] In 2009–10, these claims were unanimously rejected by the Omnibus Autism Proceedings, in which six separate administrative hearing panels found no causal relationship between vaccination and autism, either in general, as a matter of biological plausibility, or in the specific test cases litigated.[200]

Bruesewitz v. Wyeth LLC[201] was brought by the parents of Hannah Bruesewitz, who was diagnosed with residual seizure disorder, encephalopathy, and developmental delay some time after she received the third in the normal series of diphtheria, pertussis, and tetanus (DPT) immunizations. The parents sought compensation for Hannah's illness and treatment using the administrative process of the National Childhood Vaccine Injury Act.[202] When the claim was denied for failure to establish that the DPT immunization had caused Hannah's illness, the parents sued under Pennsylvania tort law, alleging *inter alia* that the DPT vaccine was defectively designed.[203] First

197. Grey, *supra* note 195, at 345, 354–55.

198. *Id.* at 347; *see also* Robert L. Rabin, *The Vaccine No-Fault Act: An Overview*, 8 IND. HEALTH L. REV. 269, 270 (2011) (Over the last twenty-five years, the incidence of "Table" and "Off-Table" claims has switched. While initially ninety percent of claims brought under the Act were Table claims, today ninety percent are Off-Table claims, leading to much more time-consuming fact-finding than was anticipated when the Act was enacted).

199. MNOOKIN, *supra* note 15, at 283–97; *see also* Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328 (Fed. Cir. 2010) (parents sought compensation on behalf of their children who allegedly suffered severe autism and gastrointestinal injuries from a combination of vaccines); Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010) (parents brought suit against the Department of Health and Human Services for vaccines that allegedly caused autism and other disorders in their children who were given the vaccines).

200. Lauren L. Haertlein, *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, 75 LAW & CONTEMP. PROBS. 211, 217–23 (2012). These proceedings are accessible through the Web site of the United States Court of Appeals for the Federal Circuit, *available at* http://www.uscfc.uscourts.gov/node/5026 (last visited Nov. 8, 2011).

201. 131 S. Ct. 1068 (2011).

202. *Id.*

203. The parents relied on the fact that shortly before Hannah received her DPT immunization, the FDA had approved a new, acellular vaccine (DTaP), which was designed in part to reduce adverse reactions to the DPT vaccine. At the time of

the United States Court of Appeals for the Third Circuit and then the U.S. Supreme Court held that the National Vaccine Injury Act preempted state law product liability claims for defective design against vaccine manufacturers.[204] Reviewing the statute's language,[205] as well as its legislative history, a majority of the Court found ample evidence that Congress intended to preempt all common law defective design claims. The Court noted the substantial regulatory oversight provided by the Act, which was focused on promoting vaccine safety, at the same time that it found that the Act "avoid[ed] costly tort litigation and the occasional disproportionate jury verdict."[206] Writing in dissent, Justice Sotomayor expressed concern that the Court's decision left "a regulatory vacuum in which no one ensures that vaccine manufactures adequately take account of scientific and technical advancements when designing or distributing their products."[207] Other critics asserted that the decision removed an important incentive for drug manufacturers to improve vaccine safety.[208]

2. *Informed Consent*

An increasing number of parents are challenging the conventional wisdom that vaccination is a public good and that *Jacobson v. Massachusetts* justifies mandatory childhood vaccination as a matter of "public necessity" under any and all circumstances. Noting that *Jacobson* was decided long before the due process clause was viewed as a robust protector of individual liberty,[209] these parents rely on the tort doctrine of informed consent, asserting that parents have the absolute right to make medical decisions for their children, including the decision about whether they should be vaccinated at all, or only for certain diseases.

Hannah's immunization, there was no DTaP version available for the third immunization. 561 F.3d at 237–38. Hannah's parents also asserted claims for negligent failure to produce a safe vaccine, negligent failure to warn, and strict liability for defective manufacturing. *Id.*

204. *Id.* at 248–52, 255; 131 S. Ct. at 1082.

205. Justice Scalia, writing for the majority, with Justice Breyer concurring, disagreed sharply with dissenting Justices Sotomayor and Ginsberg over the meaning of the preemption statute. The contested language provided that:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with a vaccine after October 1, 1988 if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1) (1987).

206. 131 S. Ct. at 1080.

207. *Id.* at 1086.

208. *See, e.g.*, Eric Helland et al., Tort Liability and the Market for Prescription Drugs (July 6, 2011) (unpublished manuscript) (*available at* http://ssrn.com/abstract=1883691).

209. *See supra* text accompanying note 105.

The essence of informed consent is that before a medical intervention takes place, the patient must be told about the risks, as well as benefits, of the intervention and its alternatives, including the alternative of doing nothing.[210] Parents have traditionally exercised the right to give informed consent on behalf of their children, and this is easy when parents agree with the physician's recommendation. However, there is long-standing friction between physicians and parents about whether parents should be presumed to act in their child's best interests. Some physicians contend that they, rather than the parents, are in the best position to identify and protect the interests of the child who is their patient.[211]

Informed consent doctrine is most commonly discussed in the circumstances of an individual patient–clinician encounter.[212] Yet some assert that informed consent still has an important role in the broader context of promoting public health.[213] Wendy Parmet argues persuasively that even when childhood vaccinations are mandatory, the central purposes underlying informed consent can still be achieved. These include the goals of enhancing patient dignity and self-determination, compensating patients injured by a medical intervention that they would have avoided had they been fully informed, preventing vaccine-related injuries whenever possible, and promoting trust, both between patients and their individual physicians and between patients and the overall public health system.[214]

Parmet explains that the purpose of informed consent is to achieve a patient's informed *assent* to a given procedure; after all, she says, the concept is not denominated "'*informed acquiescence.*'"[215] In the vaccination context, patients and parents must be given sufficient information to make an informed choice about whether to have their child vaccinated or to seek a religious or philosophical exemption. At

210. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 782–83 (D.C. Cir. 1972); Truman v. Thomas, 611 P.2d 902, 906 (Cal. 1980).

211. Comm. on Bioethics, Am. Acad. of Pediatrics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 315 (1995) (noting that "the pediatrician's responsibilities to his or her patient exist independent of parental desires or proxy consent"). In this view, there is a distinction between parents providing informed consent and their giving informed permission to treat their child, the doctor's patient.

212. *See, e.g.*, Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914), articulating the famous statement that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." *Id.* Even *Jacobson* recognized this principle to some extent, as it implied that the Massachusetts courts would read into the statute authorizing mandatory smallpox vaccination an exemption for a potential vaccine recipient who could show that the vaccine would be dangerous to him personally. Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905).

213. Parmet, *supra* note 61, at 73.

214. *Id.* at 81–107.

215. *Id.* at 84.

a minimum, CDC-approved Vaccine Information Sheets must be provided to each patient or parent at the clinical encounter in which vaccination is given.[216] In addition, information about vaccination should be widely and frequently disseminated to the public, ensuring that citizens understand how mandatory vaccination benefits both individual and public health.[217] Because some vaccinations take place through mass immunization campaigns, as occurred with polio in the 1950s and swine flu in 1976, patients must be given detailed information about the risks and benefits of a particular vaccine in order to make an informed decision about whether vaccination is appropriate in their individual circumstances.[218] Indeed, this is precisely the approach taken by public health officials who urged wide-scale immunization against influenza during the winter of 2012–13[219] in order to promote both herd immunity and injury prevention, another important goal of informed consent.[220]

A significant and closely related goal of informed consent is to compensate patients who are injured by a medical procedure to which they assented if that assent was accomplished by inadequate disclosure of the risks and benefits of the procedure.[221] Wendy Parmet argues that the goal of providing compensation is particularly important as a means of encouraging parents to vaccinate their children. When public health officials and pediatricians seek to educate parents about herd immunity and other societal benefits of vaccination and urge them to accept vaccination as one of their obligations as a members of a community, it makes sense that their children should be compensated in the rare case of a serious adverse reaction.[222]

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216. These sheets are prepared by the CDC; health care providers are required to give them to the patient under the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-26(a) (1993).

217. Parmet, *supra* note 61, at 108–10.

218. *Id.* at 96–97, discussing the facts underlying Kemp v. New Jersey, 809 A.2d 77 (N.J. 2002), in which a pregnant teenager who received the rubella vaccine and whose infant was born with severe birth defects alleged that she had not been warned about the risks of vaccination to pregnant women and their offspring. The case was litigated on the issue of sovereign immunity. *Id.*

219. *See, e.g.*, Mark Santora, *New York Declares Health Emergency*, N.Y. TIMES, Jan. 13, 2013, at A21.

220. Parmet, *supra* note 61, at 95–96.

221. *Id.* at 88–92; *see also* Canterbury v. Spence, 464 F.2d 772, 781–83 (D.C. Cir. 1972) (discussing the necessity of a duty to disclose risks dealing with medical procedures due to the patient's inherent trust in a doctor).

222. Parmet, *supra* note 61, at 89–90. This, of course, was one of the motivations of the parents in *Bruesewitz*. *See* discussion *supra* notes 194, 196. In contrast, by opting out of vaccination, some parents seek to place their children in the advantageous position of a "free rider" (benefiting from the herd immunity created by others, while not bearing any risk of an adverse reaction to vaccination themselves). Parmet, *supra* note 61, at 74.

Vaccine injuries are minimized through the extensive federal oversight of vaccine safety, discussed above, which involves the FDA, CDC, and related agencies.[223] As a result of this heightened surveillance, when vaccines have been found to cause particular adverse reactions, they have been withdrawn and improved.[224] Despite this, there remains an irreducible minimum of injuries caused by vaccines. Some parents are convinced that government oversight has not been adequate to protect their children from vaccine-caused harm, despite the extensive scientific reviews undertaken by the government showing no relationship between autism and thimerosal or autism and the trivalent measles, mumps, and rubella vaccine.[225]

These parents have been particularly disappointed in the no-fault compensation system established by the National Childhood Vaccine Injury Compensation Act of 1986 as an alternative to traditional tort litigation. This system compensates children if their injuries fall within a table of recognized vaccine-related injuries or if they can prove to an administrative tribunal that their injuries were caused by vaccination. As noted previously in a consolidated proceeding joining thousands of cases, the Omnibus Autism Proceeding, several separate administrative tribunals resoundingly rejected parents' claims that their children's autism was caused by vaccination.[226] These decisions have been upheld on appeal.[227]

In addition, it is possible that another important purpose of informed consent law—enhancing trust between health care professionals and their patients[228]—has been undermined inadvertently by the decisions in the Omnibus Autism Proceeding and the Supreme Court's decision in *Bruesewitz v. Wyeth LLC*.[229] As Louis Cooper, a noted proponent of childhood vaccination, explains, "Every time a mother holds her healthy infant to be immunized, she is demonstrating great faith

223. *See* discussion *supra* Part II.B.1.a.

224. MNOOKIN, *supra* note 15 and text accompanying notes 143–45. This happened in the early trials of the polio vaccine (the infamous Cutter Labs incident) and more recently, in the case of the rotavirus vaccine, which was found to cause intussusception, a rare but serious gastro-intestinal problem. After the VAERS and Vaccine Safety Datalink programs identified the problem, the rotavirus vaccine was redesigned to avoid it. *Id.*; *see also* Vaccines & Immunizations (June 23, 2010), CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm (stating that the RotaShield vaccine, which was the very first rotavirus vaccine, is no longer recommended for infants).

225. *See supra* text accompanying notes 39, 146–47.

226. *See* discussion *supra* subsection II.C.1.

227. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328 (Fed. Cir. 2010); Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010); *see also* Haertlein, *supra* note 200, at 223 (reaffirming that appellate courts have found no correlation between vaccinations and autism).

228. Parmet, *supra* note 61, at 97–98.

229. 131 S. Ct. 1068 (2011).

in the potential benefit and safety of the vaccine and trust in the clinician who recommended it. . . . This trust is an expression of a special social contract that is one key to the success of immunization programs."[230] When even a small number of parents believe that the government is not protecting children from vaccine-related harm, this trust is undermined. Currently, more than a fifth of all parents choose to vaccinate their children on an alternative vaccination schedule, a reflection both of their distrust of public health authorities and scientific orthodoxy and their more diffuse fears about their children's health.[231]

III. HPV VACCINATION

A. The Science of Infection with Sexually Transmitted Diseases

General parental concerns about vaccine safety have been heightened in the emotionally charged and information-challenged arena of sexually transmitted diseases (STDs). In theory—and in the popular imagination—one could protect against STDs by not engaging in risky behavior (i.e., unprotected sexual activity or intravenous drug use), but in reality this is not practicable. Whenever people engage in sexual relations, they are exposed to all of their current partner's prior sexual partners, thus exposing them to numerous STDs, including HIV, HPV, and Hepatitis B.[232] HPV is the most common sexually transmitted infection in the United States; about fourteen million people are newly infected each year, with 74% of these infections occurring among fifteen- to twenty-four-year olds.[233] DNA sampling of American women in their early twenties found that more than 44% currently have the HPV virus;[234] estimates of lifetime exposure to the

230. Louis Z. Cooper et al., *Promoting Public Trust in Immunization*, 122 PEDIATRICS 149, 149 (2008).

231. KJ Dell'Antonia, *supra* note 141.

232. *See, e.g.*, Tex. Dep't of Health, *Visual Culture and Health Posters: If You've Had Two Sex Partners*, NAT'L LIBR. OF MED. PROFILES IN SCI. (June 3, 2010), http://profiles.nlm.nih.gov/VC/B/B/F/V/ (educational poster used at the height of the AIDS epidemic). Further, in the case of Hepatitis B, if the sexual partner is an intravenous drug user, one is also exposed to anyone with whom the partner has shared a needle. *See, e.g.*, Karen H. Seal, *Risk of Hepatitis B Infection Among Young Injection Drug Users in San Francisco: Opportunities for Intervention*, 172 W. J. MED. 16 (2000); Eric E. Mast et al., *A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States*, MORBIDITY & MORTALITY WKLY. REP., Dec. 23, 2005, at 1, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm.

233. Tavernise, *supra* note 3; Fishbein et al., *supra* note 35, at S9.

234. Eileen F. Dunne et al., *Prevalence of HPV Infection Among Females in the United States*, 297 J. AM. MED. ASS'N 813, 813 (2007).

HPV virus among American women are as high as 80%.[235] Further, there is no meaningful difference in the rates of infection among women who chose to be sexually abstinent and those who do not.[236] In the last several decades, young adults have been increasingly engaging in oral and anal sex (which is sometimes not seen as "counting" as sex).[237]

When parents object to mandatory HPV vaccination, they frequently voice either religious or "family privacy" arguments that it will lead their children to engage in sex prematurely.[238] These charges are the same ones made previously against vaccination against Hepatitis B[239] and are currently voiced concerning access to emergency contraception; none of them has been borne out.[240] Studies have found that girls and young women who were immunized against HPV were no more likely than those who were not immunized to engage in sexual activity, although they were slightly more likely to practice "safe sex."[241] Similarly, several studies have found that sexually active adolescents who are given access to emergency contraception do not become more likely to engage in sexual intercourse or to be pressured into having sex.[242] As District of Columbia Councilman David Catania asserted, mandating (or even providing) vaccination against HPV is no more inviting young girls to have sex than having a tetanus shot is an invitation to children to step on a rusty nail.[243]

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235. Markowitz et al., *supra* note 5, at 4 (citing "[m]odeling estimates . . . that more than 80% of sexually active women will have acquired genital HPV by age 50").

236. *See* Lisa E. Manhart et al., *Human Papillomavirus Infection Among Sexually Active Young Women in the United States: Implications for Developing a Vaccination Strategy*, 33 SEXUALLY TRANSMITTED DISEASES 502, 505 (2006) (noting that "preventative behaviors, such as signing an abstinence pledge or correct and consistent condom use," did not predict HPV infection).

237. ARTHUR LEVINE & DIANE R. DEAN, GENERATION ON A TIGHTROPE: A PORTRAIT OF TODAY'S COLLEGE STUDENTS 63–64 (3d ed. 2012).

238. *See* Annie-Laurie McRee et al., *Mother-Daughter Communication About HPV Vaccine*, 48 J. ADOLESCENT HEALTH 314, 316 (2011).

239. *See, e.g.*, Boone v. Boozman, 217 F. Supp. 2d. 938 (E.D. Ark. 2002).

240. *See* McRee et al., *supra* note 238, at 316.

241. Robert A. Bednarczyk et al., *Sexual Activity—Related Outcomes After Human Papillomavirus Vaccination of 11- to 12-Year-Olds*, 130 PEDIATRICS 798, 798, 801–03 (2012) (citing results of a large retrospective study of American pre-adolescents, as well as studies of self-reported sexual activity among girls and young women in the United States and Australia).

242. Cynthia C. Harper et al., *The Effect of Increased Access to Emergency Contraception Among Young Adolescents*, 106 OBSTETRICS & GYNECOLOGY 483, 489–90 (2005); Melanie A. Gold et al., *The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors*, 17 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 87, 91 (2004). Indeed, one study found that adolescents who have access to emergency contraception actually increased their use of condoms. *Id.*

243. Pauline Self, *The HPV Vaccination: Necessary or Evil?*, 19 HASTINGS WOMEN'S L.J. 149, 162 (2008).

B. Reasons to Mandate Vaccination Against HPV

1. *Achieving Herd Immunity and Protecting Vulnerable Populations*

Given the reality that HPV is sexually transmitted, in a wide variety of ways, the only way to effectively reduce its spread is to mandate vaccination of all pre-adolescent and adolescent boys and girls.[244] Australia was the first country to recognize the efficacy of a universal vaccination program[245] Perhaps this was due to the serendipitous discovery that after the government made HPV vaccine free for adolescent girls and young women there was an unexpected and dramatic decrease in the incidence of HPV among adolescent boys and young men.[246] A 2013 study found that the rate of HPV infections among American adolescent girls was cut in half between 2006 and 2010, from 7.2% to 3.6%, apparently due to an increase in HPV vaccination, even though the rates of vaccination in the United States are low compared to those in other countries.[247]

Universal vaccination against HPV, as is the case with other diseases, is the only way to protect vulnerable populations, who are most likely to fall through the cracks of the health care system.[248] While about four-fifths of American women are regularly screened for cervical cancer, nearly one-fifth is not.[249] Even though the median age of women who are diagnosed with cervical cancer is forty-eight, fifteen percent of these women are less than thirty-five years old.[250] Cur-

244. *See* Liz Szabo, *Boys Should Get Routine HPV Vaccination, CDC Panel Says,* USA TODAY, Oct. 25, 2011.

245. Kirby, *supra* note 4 (noting that Australia is the first country to provide free HPV vaccination for female and male adolescents and young adults).

246. Hammad Ali et al., *Genital Warts in Young Australians Five Years into National Human Papillomavirus Vaccination Programme; National Surveillance Data,* 346 BRIT. MED. J. at 3 (2013), *available at* http://www.bmj.com/content/346/bmj.f2032.pdf%2Bhtml.

247. Tavernise, *supra* note 3.

248. *See* Jemal, *supra* note 3, at 185 (noting that "[c]ervical cancer rates were markedly elevated among most women living in low vs high socioeconomic status areas"); *see also supra* text accompanying notes 113–15, 141, 148–50 (indicating that only when vaccination is mandatory, and those mandates are enforced, are all members of the population likely to be vaccinated).

249. Markowitz et al., *supra* note 5, at 8. Eighty-two percent of American women are regularly screened. This means that, despite public perceptions that HPV screening is widespread, 18% of American women are not regularly screened; indeed some have never, or only rarely, been screened. *Id.* A study of women who were diagnosed with invasive cervical cancer found that 28% of those women had never had a Pap screening test for cervical cancer, and 23% had had their last Pap test more than five years before they were diagnosed with cervical cancer. Dwight T. Janerich et al., *The Screening Histories of Women with Invasive Cervical Cancer, Connecticut,* 85 AM. J. PUB. HEALTH 791, 793 (1995).

250. Sharon Schwartz, *Young Cervical Cancer Patients and Fertility,* 25 SEMINARS IN ONCOLOGY NURSING 259, 260 (2009).

rently, those most at risk for developing cancer as a result of contracting HPV through sexual activity are poor women of color and gay and bisexual adolescents and men.[251] Both groups frequently lack access to adequate health care. In addition, high-risk women are frequently immigrants, who are not well-integrated into American society, often lack insurance, and thus face additional barriers to obtaining health care.[252] These women are much less likely than women born in the United States both to be screened for cervical cancer and to have their cancer caught in time.[253] Significantly, nonimmigrant African-American women are also at risk, because they are slower to "clear" the HPV virus from their systems than white women.[254] They are thus more likely to develop cervical cancer and to die if their disease is not promptly discovered and treated.[255]

Every year, about fifty million American women receive a Pap smear to screen for cervical cancer.[256] Even when screening is available, it is not cost-free, either for society or for the women affected. Between seven and ten percent of these women will require further screening and often invasive testing, as well as invasive treatment.[257] In 2007, the "annual burden of cervical HPV-related diseases [was estimated to be between] $2.25 billion and $4.6 billion in the United

251. *See* Jemal, *supra* note 3, at 185, 194, 196; *see also* NAT'L CANCER INST., *Cancer Health Disparities* (Mar. 11, 2008), http://www.cancer.gov/cancertopics/factsheet/disparities/cancer-health-disparities (stating African-American/black women are more likely to be diagnosed with cervical cancer and have the highest death rate from cervical cancer).

252. *Cf.* J.A. Chilton et al., *Cervical Cancer Among Vietnamese Women: Efforts to Define the Problem Among Houston's Population*, 99 GYNECOLOGIC ONCOLOGY S203 (2005) (finding "[t]he highest age-adjusted cervical cancer incidence rate in the United States occurs among Vietnamese women").

253. *See* Jemal et al., *supra* note 3, at 188, 194 (noting that having a Pap test is negatively correlated with the incidence of cervical cancer, that women who lacked regular medical care or health insurance had low rates of Pap screening and that Asian and Hispanic women had lower rates of Pap screening than either white or black Americans). Another study found that women who were diagnosed with invasive cervical cancer were very likely not to have been adequately screened for cervical cancer. In a sample of 481 women, more than a quarter had never been screened and more than a fifth had had their last Pap smear more than five years ago. Dwight T. Janerich et al., *supra* note 249, at 793.

254. Marilyn Marchione, *Study Finds HPV Infections Last Longer in Black Women*, WASH. POST, Apr. 3, 2012, at A17.

255. *Id.*; *see also* NAT'L CANCER INST.,, *supra* note 251 (explaining cancer health disparities among different races, ethnicities, and underserved groups); The Associated Press, *Hint to Cervical Cancer's Race Divide*, DENV. POST, Apr. 2, 2012, at 8A (noting "black women are . . . much more likely than whites to develop and die from cervical cancer"). It is thus perhaps not coincidental that Henrietta Lacks, a woman with a famous connection to cancer, who died from cervical cancer, was African-American. REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

256. Markowitz et al., *supra* note 5, at 5.

257. *Id.* at 5.

States. The annual burden of cervical cancer [is] $181.5 million to $363 million."[258] In addition to the more than 4000 American women who die each year from cervical cancer, many women who survive their cancer are rendered infertile by the cancer treatment, causing significant physical and emotional distress.[259]

Gay and bisexual men are increasingly likely to develop anal, penile, and throat cancer due to HPV infection.[260] Like poor women affected by cervical cancer, these groups are often socially and economically marginalized, and many lack adequate access to health care.[261] Heterosexual men are also at increased risk of developing throat cancer due to sexually transmitted viruses, especially those caused by HPV.[262] With new information showing a dramatic increase in HPV-related cancers of the throat, penis, and anus,[263] medical authorities in the United States, the United Kingdom, and Australia are now urging that both males and females should be vaccinated against HPV.[264] Mandatory vaccination of all those likely to be infected, and harmed, by HPV is the best way to decrease the incidence of all HPV-related cancer and related health conditions.

258. Jane E. Brody, *HPV Vaccine: Few Risks, Many Benefits*, N.Y. TIMES, May 15, 2007, at F7 (quoting Rachael L. Fleurence et al., *Review of the Economic and Quality-of-Life Burden of Cervical Human Papillomavirus Disease*, 196 AM. J. OBSTETRICS & GYNECOLOGY 206, 210 (2007)). Indeed, one recent study found that many health care professionals are "over-screening," routinely using HPV screening tests as part of routine screening for cervical cancer, despite the fact that such tests do not yield any clinically useful information. Jennifer Wai-Yin Lee et al., *Low-Risk Human Papillomavirus Testing and Other Nonrecommended Human Papillomavirus Testing Practices Among U.S. Health Care Providers*, 118 J. OBSTETRICS & GYNECOLOGY 4 (2011) (noting that many providers routinely tested women for HPV when the use of such tests was not accepted clinical practice, either because the form of the HPV virus detected could not lead to cervical cancer or because the women were not in an age range where such a test would be useful).

259. *See* Lukas Rob et al., *Fertility-Sparing Surgery in Patients with Cervical Cancer*, 12 LANCET ONCOLOGY 192, 192 (2011); Jeanne Carter et al., *Gynecologic Cancer Treatment and the Impact of Cancer-Related Infertility*, 97 GYNECOLOGIC ONCOLOGY 90, 91–93 (2005); *see also* Schwartz, *supra* note 250, at 261 (noting that women with and without children are both distressed by a diagnosis of cervical cancer because of its implications for their ability to have children in the future).

260. Jemal et al., *supra* note 3, at 194; Laurance, *supra* note 23; and CENTERS FOR DISEASE CONTROL & PREVENTION, *HPV and Men—CDC Fact Sheet*, *available at* http://www.cdc/gov/std/hpv/HPVandMen-fact-sheet-February-2012.pdf (last visited Oct. 14, 2013).

261. David J. McKirnan et al., *Health Care Access and Health Behaviors Among Men Having Sex With Men: The Cost of Health Disparities*, 40 HEALTH EDUC. & BEHAV. 32 (2012), *available at* http://heb.sagepub.com/content/40/1/32.full.pdftml.

262. McNeil, *supra* note 23.

263. Jemal, *supra* note 3, at 185, 191.

264. *See, e.g.*, Harris, *supra* note 3 (describing ACIP's recommendation that all boys be vaccinated against HPV); O'Connor, *supra* note 89 (same); Laurance, *supra* note 23.

C. Does Mandatory HPV Vaccination Pass Constitutional Muster?

1. Substantive Due Process

Mandating HPV vaccination for all children and adolescents raises substantive due process and equal protection issues that should be addressed consistently with mandatory vaccination for all other diseases. Under *Jacobson v. Massachusetts*,[265] mandatory vaccination is justified by public necessity—the need to prevent the spread of a serious disease—and is permissible if the means chosen are reasonable, proportional, and minimize harm.[266]

HPV-related diseases, and the vaccine to prevent HPV infection, clearly meet this test when compared to other diseases. HPV is the most common sexually transmitted disease in the United States, affecting nearly a quarter of young people at any given time, with a lifetime incidence of nearly eighty percent.[267] Although most people shed the virus easily, a large number will not and are thus likely to develop HPV-related cancer or its precursors, particularly genital warts. Genital warts are stressful and embarrassing; cancer is a serious disease. Currently, HPV-related cancers kill nearly 6000 Americans a year, and the rates of male HPV-related cancers are rapidly rising to meet those of women, who historically were most at risk of dying from a disease caused by HPV.[268]

A comparison of the harm caused by HPV with other diseases is instructive. When the Supreme Court upheld Massachusetts's exercise of the police power to mandate smallpox vaccination, smallpox was a deadly disease, which was spread easily through airborne transmission.[269] At the time *Jacobson* was decided, Boston had just experienced a major outbreak of smallpox, in which 270 of the 1596 people who contracted smallpox had died, a fatality rate of about seventeen percent.[270] When the United States faced the polio epidemics of the mid-twentieth century, thousands of children and adults were afflicted. The *average* annual death toll from polio from 1950 until 1955, the year the Salk vaccine was introduced, was more than 1700.[271] Af-

265. 197 U.S. 11 (1905).

266. Hodge & Gostin, *supra* note 105, at 856–57 (summarizing the *Jacobson* criteria).

267. *See supra* text accompanying notes 7–8; discussion *supra* section III.A.

268. Jemal et al., *supra* note 3, at 191; Rabin, *supra* note 39.

269. *See* Aneela N. Hussain et al., *Smallpox*, MEDSCAPE (Nov. 17, 2011), *available at* http://emedicine.medscape.com/article/237229-overview (describing how smallpox is transmitted and noting that variola major, the dominant form of smallpox, has a mortality rate of thirty percent)

270. Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 577 (2005).

271. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 252 and G-1.

ter the Salk and Sabin vaccines were developed, the incidence of illness and mortality fell dramatically.[272]

Other common diseases show a similar pattern of dramatic decline in incidence, and mortality, in response to vaccination. Having the measles was a routine childhood experience for most Americans until the 1970s. Although for many children the disease's effects were short-term, with memories of a rash and a high fever the only residue, for others the disease was life-changing and life-threatening, leading to pneumonia, encephalitis, and sometimes death.[273] The measles vaccine changed all that. Before the vaccine was introduced, an average of 530,000 Americans were stricken with measles each year; in 2010 that number was reduced to sixty-one.[274] Rubella is a disease that usually does not seriously harm children, but it has severe consequences when pregnant women become infected, causing their children to be born suffering from blindness, deafness, mental retardation, and other birth defects, collectively termed congenital rubella syndrome.[275] A rubella epidemic in 1964 and 1965 afflicted more than twelve million Americans; about 20,000 babies were born with congenital rubella syndrome.[276] Since the introduction of the measles, mumps, and rubella vaccination, the incidence of rubella has declined dramatically, from an average of 47,000 cases annually in the twentieth century to six cases in 2010, effectively eliminating rubella as a source of harm to children.[277]

Finally, the example of Hepatitis B is illuminating. Hepatitis B causes approximately 5000 deaths a year due to cirrhosis and liver cancer; many thousands more suffer from chronic liver disease. Hepatitis B is transmitted at birth from mothers to newborns, as well as later in life between sexual partners and intravenous drug users.[278] Before mandatory vaccination against Hepatitis B began in the 1990s, between thirty to forty percent of all chronic Hepatitis B infections resulted from perinatal or early childhood transmissions.[279] Children younger than ten are most likely to be afflicted by Hepatitis B, but they are frequently asymptomatic so that they only become aware of their infection much later in life, when the effects of chronic infection

272. *Id.* Compared to the 1950s, when more than a quarter million Americans were stricken with polio and the annual death toll was as high as 3145, today no American dies from polio. However, there is still the need to achieve global eradication. *Id.* at G-1–G-2.

273. *Id.* at 174–75.

274. *Id.* at G-7.

275. *Id.* at 276–77.

276. *Id.* at 276.

277. *Id.* at 279, G-7.

278. Seal, *supra* note 232, at 16; Mast et al., *supra* note 232; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 120.

279. Fishbein et al., *supra* note 35, at S10.

with Hepatitis B become apparent in the form of full-blown Hepatitis B and liver cancer.[280]

In 2002, in *Boone v. Boozman*,[281] an Arkansas federal district court applied *Jacobson* to a parental challenge to mandatory vaccination against Hepatitis B. The court found that *Jacobson*'s reasoning was not limited to the threat posed by smallpox, an airborne, highly contagious, and deadly pathogen. Rather, the court found that the rationale for mandatory vaccination applied equally to diseases like Hepatitis B, which are transmitted through bodily fluids, including sexual contact and intravenous drug use.[282] The court held that it was not necessary for a targeted disease to pose "a clear and present danger" in order to uphold a particular vaccine mandate. Instead, the court found it was sufficient that the disease poses a significant health risk, afflicting a number of Americans.[283]

Deaths from HPV are less visible than those from smallpox and polio,[284] but they are no less real. They significantly exceed the death toll from measles, mumps, and rubella, even at their mid-twentieth century height, and HPV deaths are higher than the number of deaths currently caused by Hepatitis B infection—perhaps because each of these other diseases are all part of vaccination mandates in every state. Nearly eighty percent of Americans are expected to contract the HPV virus in their lifetimes; a significant number will develop cancer as a result, and about 6000 will die every year. Mandatory vaccination is a necessary, cost-effective means of protecting those whose HPV infection will progress to cancer, especially those who lack access to routine screening and other preventative health care. It thus meets *Jacobson*'s requirement of a necessary, reasonable, and proportional exercise of state police power. Mandating HPV vaccination for middle school children before they reach the age of sexual activity is essential in order to interrupt the natural disease transmission process by denying the disease a "host." HPV is no different than any other disease; the herd immunity that results from vaccination protects the entire community, especially those who are most vulnerable to the disease

280. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 20, at 115, 117 (noting that Hepatitis B is the cause of up to eighty percent of liver cancers).

281. 217 F. Supp. 2d 938 (E.D. Ark. 2002).

282. *Id.* at 954.

283. In *Boone* the court noted that approximately 1.25 million Americans suffered from chronic Hepatitis B and that about 80,000 Americans were newly afflicted each year, primarily from intravenous drug use. *Id.*

284. HPV-related deaths are potentially less visible than smallpox and polio deaths for three reasons. They do not occur as sporadic epidemics, apparently out of the blue; they are most likely to occur among adults, rather than children, due to the latency period of cancer development; and they disproportionately affect marginalized groups: immigrants, the poor, women of color, and gay and bisexual men.

and who are unable to be vaccinated.[285] Vaccination—against any disease—works because it is less costly and more successful than identifying all persons at particular risk of having or transmitting the disease.[286]

a. How to Respond to Parental Concern About HPV Vaccination

As noted above, some parents have expressed concern about the HPV vaccination on the ground that its availability would promote sexual activity on the part of vaccinated adolescents. Indeed, parental opposition to the HPV vaccine appears to be growing.[287] However, studies have shown that there is no empirical basis for this concern.[288] Other parents have worried that mandating vaccination against HPV will require them to discuss sex with their children before they are ready;[289] however, parents can frame that awkward issue in terms of avoiding cancer.[290] Notably, both the District of Columbia and Virginia, the only two jurisdictions which have mandated HPV vaccination, include a special opt-out provision that is broader and easier to obtain than the medical and religious exemptions that are available for all other vaccine-preventable diseases.[291] As a result, in both jurisdictions the rates of immunization against HPV are lower than those of other routine adolescent immunizations.[292]

285. This occurs because they are too young or old to be vaccinated or are unable to be vaccinated for medical reasons, such as the fact that they are receiving chemotherapy or immunosuppressive drugs or have a history of adverse reactions to vaccines. *See* sources cited *supra* note 27 and accompanying text.

286. This reality—that it is both too costly and too inefficient to try to vaccinate only those at high risk of contracting a particular disease—is reflected in the efforts by the Centers for Disease Control to eradicate Hepatitis B. Initial efforts to target those at high risk of Hepatitis B transmission—infected mothers and intravenous drug users—proved unsuccessful both because many people who were Hepatitis B positive were asymptomatic and unaware of their infection or they were people with limited access to the health care system and unlikely to respond to voluntary immunization efforts. *See, e.g.*, Fishbein, *supra* note 232, at S11; Mast et al., *supra* note 232. The same can be said of many people who will become infected with HPV, because of the virus's ubiquity. While many people quickly shed the HPV virus, others do not; for those who lack access to preventative health care, including routine screening, cancer is a likely outcome. *See supra* text accompanying notes 280–91; discussion *supra* Part III.B.

287. Tavernise, *supra* note 3.

288. *See* sources cited *supra* notes 38–43 and accompanying text.

289. *See* McRee et al., *supra* note 238, at 316. It is not clear if the lack of readiness is on the part of the parent or child.

290. *See* Claire McCarthy, *The HPV Vaccine: It's About Cancer, Not Sex*, MD MAMA (March 1, 2012, 12:24 PM), http://www.boston.com/lifestyle/health/mdmama/2012/03/the_hpv_vaccine_its_about_cancer_not_sex.html.

291. *See supra* notes 91, 92 and accompanying text.

292. *See supra* note 93 and accompanying text.

There is no scientific or legal reason to treat vaccination against HPV differently than all other childhood and adolescent vaccines. All vaccination mandates are directed at saving the lives of children, as well as the lives of others with whom the child will eventually come into contact. Existing state law vaccination exemptions—on medical, religious, and philosophical grounds—are more than sufficient to protect children who have a valid medical reason not to be vaccinated, as well as parents' religious and philosophical beliefs.[293] Parents have an important role in directing their children's upbringing, but they are also stewards of their children's health.[294] No matter how much parents may wish to believe that their children will always be young and innocent, the truth is that they will become adults and are highly likely to engage in sexual activity, often before the age of emancipation. The forty-year-old virgin is a rarity.

2. *Equal Protection*

The two jurisdictions that currently mandate vaccination against HPV require vaccination only for girls.[295] In part this may be an accident of history. When the District of Columbia and Virginia enacted their mandates, the FDA had licensed the HPV vaccine Gardasil® only for girls.[296] However, since 2009, both Gardasil® and Cervarix® have been licensed and approved for girls and boys,[297] and in 2011 the Advisory Committee on Immunization Practices (ACIP) went further and recommended that HPV vaccination should be mandated for both males and females.[298] Mandating vaccination for children and adolescents of both genders makes sense, given the fact that HPV is sexually transmitted. Vaccination will protect all vaccinated individuals and their ultimate sexual partners, regardless of their sexual orientation. While current HPV-related cancers claim more female than male lives,[299] a gender-related statistical disparity in the benefit to be obtained from a particular government action is insufficient to withstand an equal protection challenge.[300]

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293. *See supra* notes 119–33 and accompanying text.

294. *See, e.g.*, Prince v. Massachusetts, 321 U.S. 158 (1944).

295. *See* sources cited *supra* note 91.

296. *See* Markowitz et al., *supra* note 5, at 2.

297. *See* sources cited *supra* note 36.

298. Harris, *supra* note 3.

299. Indeed, the trend in HPV-related illness and mortality is toward gender parity; increasing numbers of male teenagers and young men are developing HPV-related cancer of the throat, anus, and penis; therefore, in the not too distant future, their numbers may meet the number of women who die of cervical, throat, urethral, vulvar, and other cancers. *See* sources cited *supra* notes 3, 36.

300. *See, e.g.*, City of Los Angeles, Dep't. of Water & Power v. Manhart, 435 U.S. 702, 708–09 (1978).

Further, requiring only girls and young women to be vaccinated against HPV perpetuates cultural stereotypes about who should be responsible for protecting against "unsafe sex." Such a mandate discriminates against women because it assumes that they, unlike men, need protection and paternalism.[301] A "female only" mandate reflects a bias in favor of heterosexual sexual activity that is increasingly subject to legal challenge.[302] Further, mandating vaccination against HPV for both genders would protect victims of rape and incest, who have no means of protecting themselves against sexually transmitted diseases.[303] In short, any effort to distinguish between males and females in terms of the need to protect their health is likely to fail because of a long line of Supreme Court cases that have declined to enshrine social stereotypes as constitutionally permissible gender discrimination.[304]

IV. CONCLUSION

In an age of anxiety, many parents, too young to have lived through the smallpox outbreaks of the early twenty-first century, the influenza pandemic of 1918, or the polio epidemics of the 1950s, have heightened, and unrealistic, concerns about the risks of vaccination compared to the harm that vaccination prevents. Parents are often distrustful of authority—be it governmental, scientific, or medical—and fearful about their own future, as well as that of their children. It is therefore understandable that some parents would be skeptical, and perhaps squeamish, about a vaccination for HPV that will protect their children against a sexually transmitted disease and a wide range of cancers. But fear and discomfort cannot be the basis for sound public health policy. Mandatory vaccination against HPV, subject to the same opportunity to seek exemption applicable to other childhood vaccinations, will save countless lives—of women *and* men—and should be adopted immediately in every jurisdiction.

301. Elizabeth J. Chen, *Equal Protection: Why the HPV Vaccine Should be Mandated for Both Boys and Girls*, 38 WASH U. J.L. & POL'Y 289, 310–13 (2012).

302. *See, e.g.*, Lawrence v. Texas, 539 U.S. 558 (2003); United States v. Windsor, 133 S. Ct. 2675 (2013); Hollingsworth v. Perry, 133 S. Ct. 2652 (2013).

303. Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1757 (2008).

304. *See, e.g.*, Craig v. Boren, 429 U.S. 190, 210 (1976) (holding that Oklahoma could not discriminate between men and women in the age at which they were old enough to buy beer); United States v. Virginia, 518 U.S. 515, 535 (1996) (striking down the Virginia Military Institute's refusal to admit women).